Formative Evaluation of the Canadian HIV Vaccine Initiative

Final Report

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Public Health Agency of Canada

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Foreword

The Canadian HIV Vaccine Initiative (CHVI) formative evaluation was conducted to measure the progress of the first two years of the initiative. The data collection phase occurred between May and August 2009. A number of areas requiring improvement were identified, namely delays in implementing CHVI funding programs and processing transfer payments between departments, and the need for a revised governance structure and performance measurement system.

Since August, the CHVI has undergone substantial changes. On February 19, 2010, a joint decision was made by the Government of Canada and the Bill & Melinda Gates Foundation not to move forward with the pilot-scale manufacturing facility for clinical trial lots. The current CHVI components are unaffected by this decision and will continue to be implemented.

A Memorandum of Understanding has been developed by the Government of Canada and the Bill & Melinda Gates Foundation to renew the CHVI with additional activities to take the place of the facility component. The new activities include the establishment of the CHVI Research and Development Alliance and the prevention of mother-to-child transmission of HIV. The initiative will be implemented over six years, from 2010-11 to 2016-17 with total funding of $139M. In support of the renewed initiative, a revised governance structure has been put in place that encompasses senior officials from the five CHVI participating departments and agencies as well as the Bill & Melinda Gates Foundation as key decision makers.

Since the CHVI formative evaluation was completed, progress has been made in a number of areas:

- The Emerging Team Grants funding opportunity has been completed and two teams have been awarded funding by CIHR;
- The Large Team Grants funding opportunity was launched in summer 2010 by CIHR and CIDA;
- The Clinical Trial Capacity Building Funding Opportunity, administered under the Global Health Research Initiative, has been completed and seven teams have been awarded funding;

- A WHO project to build sustainable regulatory capacity in low and middle-

income countries was funded by CIDA;

- Funding has been awarded to seven community projects under the Community Initiatives funding opportunity;
- The CHVI has provided support to the Global HIV Vaccine Enterprise's 2009 research conference and other Global HIV Vaccine Enterprise program activities related to the renewal of the global scientific strategic plan.

For further information on the CHVI, visit the website at: http://www.chvi-icvv.gc.ca.

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Acronyms

AAVP	African AIDS Vaccine Programme
AVAC	AIDS Vaccine Advocacy Coalition
CIDA	Canadian International Development Agency
CIHR	Canadian Institutes of Health Research
CHVI	Canadian HIV Vaccine Initiative
GoC	Government of Canada
GHRI	Global Health Research Initiative
HC	Health Canada
HVTN	HIV Vaccine Trials Network
IAVI	International AIDS Vaccine Initiative
IC	Industry Canada
LMICs	Low and middle-income countries
MOU	Memorandum of Understanding
NIH	National Institutes of Health (U.S.)
PAA	Program Activity Architecture
PHAC	Public Health Agency of Canada
NGO	Non-governmental organization
RBAF	Risk-based Audit Framework
RFA	Request for Applications
RFP	Request for Proposals
RMAF	Risk Based Management and Accountability Framework
SSP	Scientific Strategic Plan

Executive Summary

The Canadian HIV Vaccine Initiative (CHVI) (referred to as the "Initiative") is a horizontal collaboration between various Government of Canada departments and agencies and the Bill and Melinda Gates Foundation and is led by the Public Health Agency of Canada (PHAC). This evaluation was conducted between May and August 2009 by Goss Gilroy Inc., on behalf of the Public Health Agency of Canada (PHAC). It was completed as a requirement of the Integrated Based Management and Accountability Framework and Risk-based Audit Framework (RMAF/RBAF), which called for a mid-term evaluation prior to the completion of the third year of the Initiative (2010).

The evaluation examined the progress made to date by the Initiative and determined if changes are required to the design, delivery and direction of the activities. The methodology included a review of key program documents; in-person or telephone interviews with 20 internal stakeholders from the CHVI Secretariat and all participating Government of Canada departments (Canadian International Development Agency, Industry Canada, Canadian Institutes of Health Research, PHAC, Health Canada); and telephone interviews with twenty international and domestic external stakeholders with expertise in specific CHVI-related domains.

The purpose of the CHVI is to mobilize domestic and international resources to contribute to the global efforts to accelerate the development of effective and globally accessible HIV vaccines. It is composed of four program components:

- Discovery and social research;
- Pilot scale manufacturing capacity for clinical trial lots;[1]
- Clinical trial capacity building and networks; and
- Policy and regulatory issues, community and social dimensions.

In addition, a fifth component covers the planning, coordination and evaluation that is the responsibility of the CHVI Secretariat. The Secretariat, housed in PHAC, is responsible for the coordination of the Initiative, implemented by five federal government departments/ agencies – Canadian International Development Agency (CIDA), Public Health Agency of Canada (PHAC), Industry Canada (IC), Canadian

[1] On 19 February 2010, the decision not to proceed with the facility was announced jointly by the GoC and the Gates Foundation. At the time of finalizing this report, the evaluation team was aware that a recommendation to this effect had been made. However, this occurred after the completion of the data collection for this evaluation. See http://www.chvi-icvv.gc.ca/index-eng.html Accessed April 2010

Institutes of Health Research (CIHR) and Health Canada (HC) – and maintaining the relationship with the Bill & Melinda Gates Foundation.

The total allocation for the Initiative is $139M: $85M in new funding, $26M in funding that was re-profiled from the Public Health Agency of Canada's Federal Initiative for HIV/AIDS and $28M from the Bill & Melinda Gates Foundation. Although the original intent was that the CHVI be a five-year initiative, the current projections are that the funds will be spent over nine years. Yet no provisions are in place for the continuance of the Initiative beyond the five-year timeframe.

Relevance

The CHVI is well aligned with global needs and priorities and, specifically, with the Global HIV Vaccine Enterprise's 2005 Scientific Strategic Plan (SSP). As such, it provides the Government of Canada (GoC) with a mechanism to build on Canadian capacity and contribute to the well-accepted global efforts to develop an HIV vaccine. In addition, the Initiative is relevant to both Canada's domestic and international programming. Domestically, the Initiative is consistent with other Canadian HIV/AIDS activities and Canada's support for building a world-class health-related research environment, including, particularly, vaccine research and development. External stakeholders did question the balance of efforts among the CHVI components, noting the importance of continuing with basic research and addressing the regulatory framework for vaccine trials. In addition, the creation of the CHVI as a horizontal initiative allowed the GoC to integrate funding from different departments/ agencies and enhance collaboration among the various partners. The CHVI components are also well aligned with Canada's relative strengths in the HIV vaccine field and were consistent with the Program Activity Architectures of the participating departments/agencies. However, the Initiative design does not reflect adequately how the participating departments/agencies were expected to work together collaboratively to achieve the Initiative's objectives.

Evaluation Findings by Component

With the exception of the limited policy work being done by the CHVI Secretariat, most of the Initiative's activities are implemented through the not-for-profit sector – notably the academic and research communities and HIV/AIDS NGOs. All four CHVI program components rely heavily on transfer payments, through grants or contributions, with academics, researchers and NGOs. There were, at times, very significant delays in the launching of, and decision-making for, some of these transfer

payments. As a result there is considerable frustration within the HIV/AIDS community about the apparent lack of progress on Canada's contribution to the global efforts to develop an HIV vaccine. In addition, these delays have put into question the extent to which the Initiative can achieve the expected results within the remaining timeframe for the Initiative.

Not only have there been delays in the implementation of all components, but some components have also not experienced the expected results for their activities to date. There was limited response to the Community Initiative Fund, which was attributed to limitations in the HIV community's engagement in vaccine research issues. PHAC has already adjusted its approach to working with HIV community organizations to strengthen their engagement in the Initiative.

Generally speaking, most internal and external stakeholders felt that there was a need to reassess the balance of efforts among the CHVI components – particularly the emphasis on the pilot scale manufacturing capacity for clinical trial lots component following the failure of a promising HIV vaccine candidate in the fall of 2007. They felt that greater emphasis should have been put primarily on basic research and discovery as well as on regulatory issues, as both are critical, with other components, to ensure global access.

Planning, Coordination and Evaluation

Stakeholders' views of the Initiative's internal and external communications were mixed. On the one hand, there were very positive assessments of the broad consultations on funding programs with external stakeholders held in February 2008. On the other hand, external stakeholders were frustrated with delays in the implementation of funding grants and the apparent lack of communication or transparency on the progress and processes of funding applications, decisions and internal decision-making.

Internal interview respondents were generally positive about the internal coordination of the Initiative and noted particularly the extent to which the Secretariat had adapted its role to meet the needs of the interdepartmental committees. However, some challenges were reported due to limited capacity of some department/ agencies to engage in the CHVI, as well as challenges inherent in horizontal initiatives, including the challenges of partnerships among departments/ agencies with different mandates, priorities and programming requirements.

In spite of the demonstrated links between the Initiative's components and the Program Activity Architectures[2] of the participating departments/agencies, some internal stakeholders reported different degrees of congruence between some CHVI components and the mandate of their own department/agency. As a result, there was little evidence of collaboration among participating departments/agencies. In addition, these departments/agencies have different programming requirements, which made joint decision-making challenging. The delays experienced by all four program components were, to some extent, attributable to the challenges of interdepartmental approval processes.

Governance and Performance Measurement

The governance mechanisms (e.g. the CHVI Secretariat, the interdepartmental committees) have been generally effective, although the stakeholder interviews and a review of Committee minutes suggests that the Interdepartmental Steering Committee has not been sufficiently proactive and does not focus enough on strategic issues.

PHAC and the Secretariat have achieved much in the first year and a half of the Initiative. The Secretariat has become fully staffed and its role has evolved based on the needs of the Initiative. However, a need still exists for technical capacity in the Secretariat. The Secretariat has taken on more leadership and has learned lessons with respect to the management of the Initiative – notably with respect to its interactions with the participating departments. It has adapted its internal communication strategy to better meet the needs of the different partners.

A performance measurement strategy was put in place when the CHVI was approved. However, some activities foreseen in that strategy have not been fully implemented and this is expected to be a challenge at the time of the next evaluation. In addition, the Initiative's logic model does not clearly identify the linkages between the CHVI components and, as a result, does not contribute to strengthening the synergies among participating departments/agencies.

Recommendations

[2] Program Activity Architecture is a "program inventory that hierarchically links all departmental programs to the department's Strategic Outcomes." "Management, Resources and Results Structure Policy", Lydia Scratch, Political and Social Affairs Division, Library of Parliament, 23 August 2005, p. 1

Based on these findings, it is recommended that:

1. The Interdepartmental Steering Committee take the opportunity of the recommendation of the Government of Canada and the Bill & Melinda Gates Foundation to not proceed with the Pilot Scale Manufacturing Capacity for Clinical Trial Lots component to re-examine the nature and scope of the Initiative and, as individual departments/agencies, to re-examine their commitments to, and roles in, the Initiative, as well as the role of the Bill & Melinda Gates Foundation.
2. The Interdepartmental Steering Committee seek an extension of the Initiative beyond 2012/13, ensuring that there is sufficient flexibility in the Initiative to allow it to remain consistent over time with the global efforts to achieve an HIV vaccine.
3. As part of the re-examination of the nature and scope of the Initiative, the Interdepartmental Steering Committee identify clear expectations and timelines with respect to the delivery responsibilities of the participating departments/agencies in order to overcome the factors that have contributed to the delays to date in the Initiative.
4. The Interdepartmental Steering Committee put in place measures to communicate effectively with external stakeholders, through both the CHVI website and clear messaging from the participating departments/agencies.
5. The Interdepartmental Steering Committee re-examine the structure of the CHVI governing bodies, notably the Interdepartmental Steering Committee, to ensure that there is adequate authority and capacity to provide the necessary interdepartmental leadership.
6. The Secretariat, working with the program-level Interdepartmental Committee, review the existing CHVI performance framework to ensure that it remains relevant and clearly identifies department/agency responsibilities for all components and the logic model specifically identifies the links across components to the outcomes; and ensure that the performance framework is implemented to provide sufficient data for the next evaluation.

1.0 Introduction

This report reflects the results of a formative evaluation of the Canadian HIV Vaccine Initiative (CHVI) (referred to as the "Initiative") carried out between May and August 2009 by Goss Gilroy Inc., on behalf of the Public Health Agency of Canada (PHAC). After this introduction, the report is structured as follows:

- Section 2.0 – an overview of the CHVI objectives and structure, a profile of CHVI components and the roles of participating Government of Canada (GoC) departments/agencies;
- Section 3.0 –the evaluation methodology, including a discussion of the limitations of this methodology;
- Section 4.0 – the evaluation findings; and
- Section 5.0 – the conclusions and recommendations.

2.0 Context and Overview of CHVI

In 2007, the CHVI was established as Canada's contribution to the Global HIV Vaccine Enterprise. It is a collaborative effort between the GoC and the Bill & Melinda Gates Foundation and part of Canada's global commitment to accelerate the development of safe, effective, affordable and globally accessible HIV vaccines.

2.1 CHVI Context

The CHVI was created to build on Canada's strengths to support the Global HIV Vaccine Enterprise (Global Enterprise).[3] The Global Enterprise, founded in 2004, is an alliance of independent organizations, governments, and stakeholders dedicated to the development of preventive HIV vaccines. It developed and implemented a shared Scientific Strategic Plan (SSP), which focused on expanding research, increasing global capacity for manufacturing high quality clinical trial lots for HIV vaccines, building capacity to conduct large-scale clinical trials, reinforcing developing country expertise for reviewing and approving clinical trials and assessing results and establishing strategies to manage intellectual property issues.

Canadian HIV researchers, with representatives from the private and public sectors, met with Bill & Melinda Gates Foundation officials in October 2005 to explore how Canada could contribute to the SSP to further progress towards the development and delivery of HIV vaccines. This meeting and subsequent interdepartmental discussions culminated in the signing of a Memorandum of Understanding (MOU) between the Minister of Health, the Minister of International Cooperation, the Ministry of Industry and the Bill & Melinda Gates Foundation in August 2006. This MOU focused on delivering results in areas that harmonize Canada's areas of HIV vaccine expertise with the gaps identified in the SSP.

The CHVI is the vehicle to implement this MOU. It represents a coordinated domestic and international contribution to global HIV vaccine efforts and is linked to international bodies such as the International AIDS Vaccines Initiative, the World Health Organization and the Joint United Nations Program on AIDS. Policy authority was granted in January 2007 and a joint announcement on the initiative was

[3] This description of the context draws extensively from the "Integrated Result-Based Management and Accountability Framework and Risk-based Audit Framework", undated, p. 6. This framework accompanied a document that was approved in June 2007.

made on 20 February 2007, by the Bill & Melinda Gates Foundation and the Prime Minister.

2.2 CHVI Objectives and Structure

2.2.1 CHVI Objectives

The CHVI is a six-year (2007/08 to 2012/13) $139M initiative. Its objectives and program activities reflect four guiding principles: (1) strategic coordination and integration, (2) multi-sectoral collaboration and engagement, (3) promotion of human rights and global access, and (4) accountability and transparency.[4] The overall purpose of the CHVI is to implement the MOU between the GoC and the Bill & Melinda Gates Foundation by mobilizing domestic and international resources to contribute to the global efforts to accelerate the development of effective and globally accessible HIV vaccines.[5] More specifically, the CHVI objectives are to:

- Strengthen HIV vaccine discovery and social research capacity;
- Strengthen clinical trial capacity and networks, particularly in low and middle-income countries (LMICs);
- Increase global pilot scale manufacturing capacity for HIV vaccine clinical trial lots;
- Strengthen policy and regulatory approaches for HIV vaccines, particularly in LMICs;
- Promote the community and social aspects of HIV vaccine research and delivery; and
- Ensure horizontal collaboration within the CHVI and with domestic and international collaborators.[6]

The CHVI was expected to strengthen both domestic and international capacity and expertise and achieve the following results:

- Increased HIV research and capacity in Canada and in LMICs;
- Strengthened clinical trial capacity in LMICs;
- Canadian-based pilot scale manufacturing facility to produce clinical trial lots for

[4] CHVI Website (http://www.chvi-icvv.gc.ca/gp-ld-eng.html)
[5] "Integrated Result-Based Management and Accountability Framework and Risk-based Audit Framework" (RMAF/RBAF), undated, p. 7
[6] CHVI Website (http://www.chvi-icvv.gc.ca/gp-ld-eng.html)

clinical trials to be performed mostly in LMICs where the incidence and prevalence of HIV/AIDS are the highest;

- Enhanced policy and regulatory expertise in Canada and particularly in LMICs where clinical trials will be conducted and vaccines will ultimately be made available; and
- Expanded capacity to integrate community and social dimensions into HIV vaccines development and delivery efforts.[7]

The CHVI logic model is provided in Appendix A. The outcomes reflected in the logic model are similar but not identical to these results statements.

2.2.2 CHVI Governance Structure

Five federal departments and agencies are implementing the CHVI in collaboration with the Bill & Melinda Gates Foundation. These partners planned to collaborate with each other to deliver on the objectives of the CHVI, in line with their own mandates. Exhibit 2.1 outlines the roles of each department and agency.

The Minister of Health (as the Minister for PHAC), in consultation with the Ministers of Industry and International Cooperation, is the lead Minister for the CHVI. The governance bodies included (see also Exhibit 2.2):[8]

- ***Interdepartmental Steering Committee*** composed of representatives from IC, CIDA, HC, CIHR and PHAC. The Committee is co-chaired by PHAC and CIDA. The Steering Committee is responsible for providing strategic directions and priorities, reviewing progress, and establishing and maintaining linkages with identified collaborators (such as the Bill & Melinda Gates Foundation);
- ***Interdepartmental Committee*** (program level) reports to the Interdepartmental Steering Committee. It is co-chaired by PHAC and CIDA and includes representatives from all participating departments/agencies. Its role is to ensure effective coordination of the CHVI at the working level, through sharing information, coordinating program planning and policy development activities, and monitoring and reporting on CHVI; and

[7] RMAF/RBAF, p. 6 – 7
[8] RMAF/RBAF, p. 9 – 10.

Exhibit 2.1: Roles of Partner Departments and Agencies in CHVI[9]

Department	Role	Discovery & Social Research	Pilot Scale Manufacturing Capacity	Clinical Trials Capacity Building	Policy and Regulatory Issues, Community and Social Dimensions	Planning, Coordination and Evaluation
Canadian International Development Agency (CIDA)	Provide effective linkages to international development efforts Ensure consistency with Canada's international commitments	✓	✓	Lead	✓	✓
Public Health Agency of Canada (PHAC)	Lead agency and focal point for implementation of CHVI Provides secretariat support; coordinates and manages governance and management structures; and facilitates collaboration with domestic and international stakeholders Contributes scientific, policy and program expertise in public health and builds on past HIV/AIDS and vaccine initiatives Facilitates planning and coordination with Canadian and international HIV vaccine research and development partners as well as evaluation of its activities to ensure that Canada's contribution to the Global HIV Vaccine Enterprise is effective	✓	Lead	✓	Lead	Lead
Industry Canada (IC)	Contributes industry specific knowledge and experience relevant to the Canadian and international vaccine industry and assists with industry-related issues, including the appropriate engagement of potential private sector partners		✓			✓
Canadian Institutes of Health Research (CIHR)	Engages the Canadian research community and brings critical expertise in the development of strategic funding opportunities, peer review mechanisms and related professional support services to identify and fund eligible HIV vaccine projects.	Lead				✓
Health Canada (HC)	Contributes expertise in vaccine-related policy, regulations and protocols, including ethical, legal and social policy research and analysis, and facilitates networks of specialists to enhance international collaborations.				✓	✓
Bill & Melinda Gates Foundation	Partner in the CHVI, collaborating to establish a facility in Canada that will be used to manufacture promising HIV vaccines for clinical trials		✓			

[9] *Canadian HIV Vaccine Initiative Annual Report, 2008-2009*, March 30th, 2009 draft

- ***CHVI Secretariat***, housed at PHAC, works in close collaboration with participating departments/agencies to ensure a coordinated cohesive approach. The Secretariat provides operational support, coordination and planning of activities for the interdepartmental committees and contributes to partnership and stakeholder engagement. It is also responsible for monitoring, reporting and evaluation.

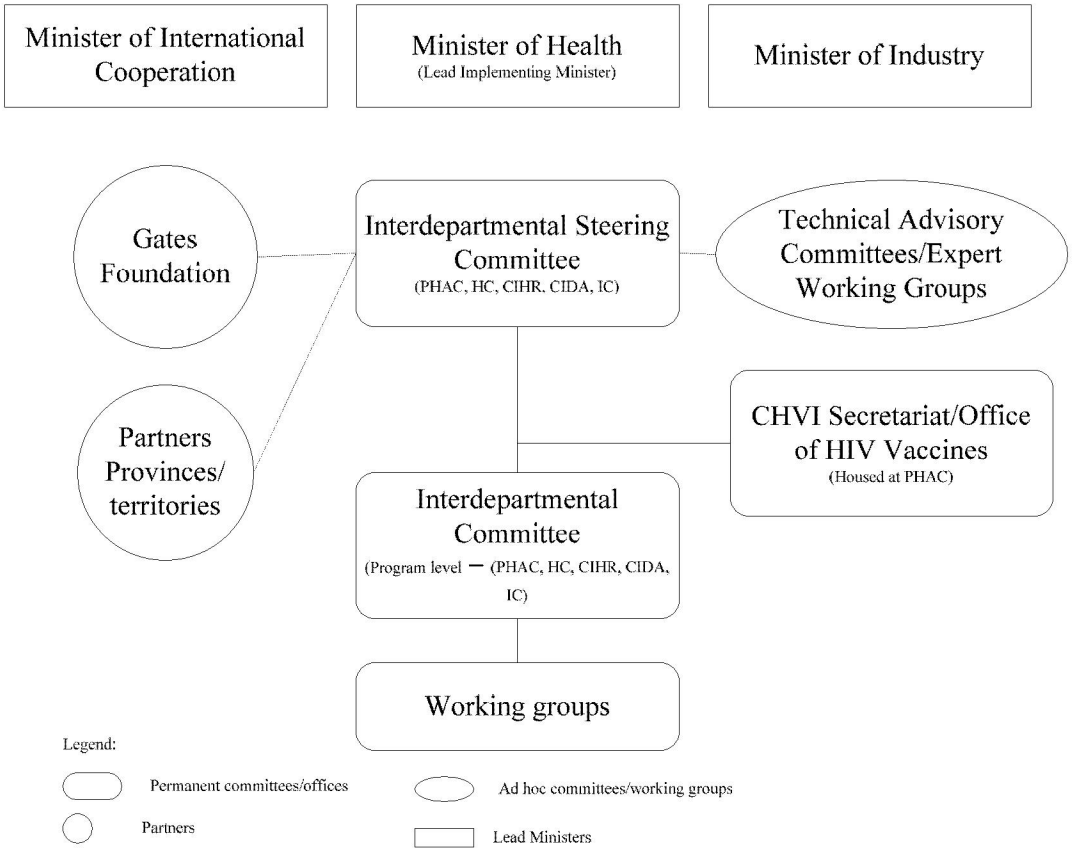
Expert working groups, identified by the Steering Committee, were formed on specific issues, as required, to engage both domestic and international key stakeholders. One such expert working group was set up for the review of the applications for the Pilot Scale Manufactory Capacity for Clinical Trial Lots component. In addition, the program-level Interdepartmental Committee has established working groups for specific tasks (e.g. communications) and *ad hoc* working groups have been established for the design of most grant or contribution programs.

The Results-based Management Accountability Framework/Results-Based Audit Framework (RMAF/RBAF)[10] foresaw also the establishment of an Advisory Committee to ensure active involvement by governments, the private sector, international stakeholders, people living with HIV/AIDS, researchers and NGOs and relevant stakeholders. Although a Chair for the committee was announced, at the time of this evaluation, no further action had been taken on this Committee.

In addition, the development of a formal federal/provincial/territorial (F/P/T) engagement strategy was planned, in order to build on existing F/P/T networks for informing provincial and territorial collaborators about the CHVI. This was expected also to serve as a forum to explore opportunities for collaboration.

[10] An RMAF is "A document which outlines the rationale, theory, resources and governance and accountability structures of a program policy or initiative and sets out a plan to measure, monitor and report on results throughout the lifecycle of the policy, program or initiative.", "Results-Based Management Lexicon", Treasury Board Secretariat, http://www.tbs-sct.gc.ca/cee/pubs/lex-eng.asp, Accessed March 2010. An RBAF "provides for identification of level-of-program monitoring and of sources of risk; assessment of the likelihood and impact of those risks, including the underlying assumptions made; and a discussion of risk mitigation actions (including management controls) taken and planned.", "A Guide to Preparing Treasury Board Submissions, Appendix D: More Information on the "Remarks" Section", http://www.tbs-sct.gc.ca/pubs_pol/opepubs/TBM_162/gptbs-gppct09-eng.asp. Accessed March 2010

Exhibit 2.2: CHVI Governance Structure



2.3 CHVI Components

2.3.1 Description of CHVI Components

In order to fulfill its objectives, the CHVI has four program components:

- Discovery and social research;
- Clinical trial capacity building and networks;
- Pilot scale manufacturing capacity for clinical trial lots; and
- Policy and regulatory issues, community and social dimensions.

The planning, coordination and evaluation activities of the Program were considered into a fifth component for the purposes of the allocation of CHVI resources; however, it is not considered a programming component. The purpose of, and activities carried

out in, each component are described in greater detail in the following sections.

Discovery and Social Research

The objective of the Discovery and Social Research component is to promote greater collaboration between researchers in Canada and LMICs who are working in HIV vaccine discovery and social research. To maximize the potential for important scientific discoveries, a multi-pronged approach is being used to support creativity through a series of research grants available to both individual investigators and collaborative teams. These include:

- ***Catalyst Grants*** provide short-term seed money to support innovative HIV vaccine-related research activities that are expected to contribute to the development of new proposals, tools, techniques, inventions or methodologies.
- ***Operating Grants*** provide funding for Canadian researchers with an interest in basic and social research related to HIV vaccines, to enhance research in HIV prevention and build future Canadian research capacity in the field.
- ***Emerging Team Grants*** support the work of Canadian research teams and their efforts to strengthen capacity, develop expertise and strategies for knowledge translation and exchange, provide a superior training and mentoring environment, and create mechanisms for individual investigators and teams funded under the initiative to network and share information with one another.
- ***Large Team Grants*** support the work of teams of Canadian and LMIC researchers in their efforts to contribute important knowledge to the global search for HIV vaccines, build capacity (human and infrastructure) for HIV vaccines discovery and related social research in Canada and in LMICs, provide opportunities for new and young investigators and create mechanisms for teams funded under the Initiative to network and share information with one another.

CIHR has the lead on the Discovery and Social Research component. Funding for the Large Team Grants comes jointly from CIHR and CIDA.

Clinical Trial Capacity Building and Networks

The purpose of this component is to strengthen the capacity of researchers and research institutions to conduct high-quality clinical trials and build site capacity to undertake clinical trials of HIV vaccines and other preventive technologies in LMICs. Funds were to be channelled through the Global Health Research Initiative (GHRI)

for "Capacity Building" and "Synergy and Networking" grants to researchers and research institutions, particularly in LMICs.

CIDA has the lead on this component and is providing the $16M for the component. The funds are to be transferred to IDRC, which will administer the grants through its regular GHRI.

Pilot Scale Manufacturing Capacity for Clinical Trial Lots

The purpose of this component was to increase the global capacity to produce HIV vaccines for use in clinical trials to be conducted mostly in, and for the benefit of, LMICs.[11] This was expected to be implemented through the establishment of a dedicated pilot scale manufacturing facility in Canada to produce candidates for clinical trials. A not-for-profit corporation (with private sector and other partners) would build and operate the facility. The identification of the team to create this facility was ongoing during the data collection for this evaluation. PHAC had the lead on this component; however funding was also to come from CIDA, IC and the Bill & Melinda Gates Foundation. The total funding was $89M.

Policy and Regulatory Issues, Community and Social Dimensions

The purpose of this component is to address policy, regulatory, community and social dimensions related to the development of a safe, effective, affordable and globally accessible HIV vaccine. It includes a number of related activities:

- Strengthening of vaccine policy approaches that promote global access to HIV vaccines;
- Enhancement of the regulatory pathway and processes for HIV vaccines in LMICs;
- Collaboration with partners in Canada and in LMICs in advancing legal, ethical and human rights dimensions of HIV vaccines; and
- Strengthening existing mechanisms to support community involvement in vaccine research and development, clinical trials and activities related to public awareness and education.

[11] On 19 February 2010, the decision not to proceed with the facility was announced jointly by the GoC and the Gates Foundation. At the time of finalizing this report, the evaluation team was aware that a recommendation to this effect had been made. However, this occurred after the completion of the data collection for this evaluation. See http://www.chvi-icvv.gc.ca/index-eng.html Accessed April 2010

PHAC, CIDA and HC are engaged in this component.

Planning, Coordination and Evaluation

The last component – although not strictly a program component –covers the CHVI planning, coordination and evaluation. Its purpose is to ensure effective strategic planning, scientific oversight, coordination and evaluation to meet CHVI objectives. Tasks include:

- Establishing and maintaining the CHVI governance structure;
- Monitoring key trends in HIV vaccine research and development;
- Enhancing Canada's contribution to the global efforts by mobilizing expertise, partnerships, resources and liaising with domestic and international stakeholders;
- Establishing new partnerships and promote stakeholder engagement in the CHVI;
- Raising the profile of the CHVI among stakeholders in Canada and internationally and to communicate progress;
- Providing secretariat support to the Initiative, including its Interdepartmental Steering Committee and multi-stakeholder advisory committee; and
- Reporting on CHVI progress.

PHAC has the lead on this component and is responsible for funding the planning, coordination and evaluation activities. However, all partner departments/agencies contribute to the component, primarily through their participation in the governance structures.

2.4 CHVI Financial Profile

Exhibits 2.3 and 2.4 reflect the CHVI financial profile. Exhibit 2.3 reflects the initial total allocation for the Initiative – $85M in new funding, $26M in funding that was reprofiled from PHAC's Federal Initiative for HIV/AIDS and $28M from the Bill & Melinda Gates Foundation, for a total of $139M.

Exhibit 2.3: CHVI Investments (2007 – 2013)

Component	HC	CIHR	PHAC	IC	CIDA	Gates	Total
Discovery and Social Research		$10M*			$12M		$22M
Clinical Trial Capacity Building					$16M		$16M
Clinical Trial Lot Manufacturing			$12M				$89M
			$6M*	$13M	$30M	$28M	
Policy/Regulatory/ Community/ Social	$1M*		$5.5M*		$2M		$8.5M
Planning/Evaluation			$3.5M*				$3.5M
Total	$1M	$10M	$27M	$13M	$60M	$28M	$139M

Source: CHVI Secretariat, November 2009

* Funding that was reallocated from the Federal Initiative for HIV/AIDS ($26M). The remaining funds were newly invested funds for CHVI.

CIDA is the largest contributor to the Initiative, with contributions to four components, accounting for 43% of the total investment (including the Bill & Melinda Gates Foundation) and 53% of the GoC investment.

The actual expenditures, compared to the amounts allocated in the approved program authority document, are shown in Exhibit 2.4. This exhibit also reflects the CHVI Secretariat's revised plan for the Initiative, if it is extended to 2015/16. No authorities are yet in place for the continuance of the Initiative beyond the five-year timeframe. (Note that Exhibit 2.4 does not include the expected $28 M from the Bill & Melinda Gates Foundation.)

Analysis of the differences between the approved commitments, on a year by year basis, and actual expenditures, reflects the significant delays in the implementation of the CHVI:

- The first year of the Initiative (2007/08) was planned to be a development year and, as a result, expenditures were expected to be lower than in the following years. Yet, the actual expenditures were considerably lower than the modest amount planned – 63% of the $1.5 million planned for the year;
- Expenditures for the first two years of full programming (2008/09 ad 2009/10) reflect significant under-spending, compared to approved commitments. In 2008/09, actual expenditures represented only 11% of planned expenditures and in 2009/10, the revised planned expenditures will be only 15% of the approved commitments for that year; and
- All program components (excluding Planning, Coordination and Evaluation) saw major lapses in spending compared to approved commitments for these two years.

These financial figures reflect the delays in implementation of the Initiative.

Exhibit 2.4: Allocation of Government of Canada Financial Resources by Component, Comparing the Planned to Actual Expenditures and Revised Plans, 2007/08 to 2010/11[12]

Program Area	2007-08		2008-09		2009-10		2010-11	
	Planned	Actual	Planned	Actual	Planned	Revised Plan	Planned	Revised Plan
Discovery and Social Research								
CIHR/IRSC	500,000	110,000	2,000,000	682,624	2,000,000	1,416,942	2,000,000	1,254,019
CIDA	0	0	2,400,000	0	2,400,000	0	2,400,000	1,200,000
Clinical Trial Capacity Building and Networks								
CIDA	0	0	3,200,000	388,163	3,200,000	1,000,000	3,200,000	3,500,000
Policy and Regulatory Issues, Community and Social Dimensions								
Health Canada	200,000	180,000	200,000	0	200,000	0	200,000	260,000
PHAC	223,600	46,600	1,185,000	341,627	1,185,000	1,455,373*	1,435,000	1,185,000
CIDA	0	0	500,000	0	500,000	400,000	500,000	400,000
Planning, Coordination and Evaluation								
PHAC	426,000	426,000	738,000	738,000	738,000	738,000	738,000	738,000
Non-facility sub-total	1,349,600	762,600	10,223,000	2,150,414	10,223,000	5,010,315	10,473,000	8,537,019
Pilot Scale Manufacturing Capacity for Clinical Trial Lots								
PHAC	206,400	206,400	238,000	238,000	8,738,000	238,000	8,738,000	8,738,000
Industry Canada	0	0	3,250,000	0	3,250,000		3,250,000	3,250,000
CIDA	0	0	2,750,000	0	12,250,000		12,250,000	12,250,000
Total	1,556,000	969,000	16,461,000	2,388,414	34,461,000	5,248,315	34,711,000	32,775,019

Source: CHVI Secretariat, December 2009

* Does not include an additional $495,850 provided by PHAC to support the Global HIV Vaccine Enterprise

Note: All figures for future spending of GoC departments were based on projections made for the original 5-year duration of the initiative.

[12] Not including the $28M contribution from the Gates Foundation

Exhibit 2.4: Allocation of Government of Canada Financial Resources by Component, Comparing the Planned to Actual Expenditures and Revised Plans (cont'd), 2011/12 to 2015/16

Program Area	2011-12		2012-13		2013-14	2014-15	2015-16	Total
	Planned	Revised Plan	Planned	Revised Plan	Rev Plan	Rev Plan	Rev Plan	Planned
Discovery and Social Research								
CIHR/IRSC	2,000,000	2,243,353	1,500,000	1,753,743	1,550,000	1,550,000	560,681	10,000,000
CIDA	2,400,000	2,400,000	2,400,000	2,400,000	2,400,000	3,600,000	0	12,000,000
Clinical Trial Capacity Building and Networks								
CIDA	3,200,.000	3,500,000	3,200,000	3,500,000	4,111,837	0	0	16,000,000
Policy and Regulatory Issues, Community and Social Dimensions								
Health Canada	200,000	280,000	0	280,000	0	0	0	1,000,000
PHAC	1,435,000	1,435,000	0	1,000,000	0	0	0	5,463,600
CIDA	500,000	400,000	0	400,000	400,000	0	0	2,000,000
Planning, Coordination and Evaluation								
PHAC	738,000	738,000	0	0	0	0	0	3,378,000
Non-facility sub-total	10,473,000	10,996,353	7,100,000	9,333,743	8,461,837	5,150,000	560,681	49,841,600
Pilot Scale Manufacturing Capacity for Clinical Trial Lots								
PHAC	238,000	8,738,000	0	0	0	0	0	18,158,400
Industry Canada	3,250,000	3,250,000	0	3,250,000	3,250,0000	0	0	13,000,000
CIDA	2,750,000	12,250,000	0	5,500,000		0	0	30,000,000
Total	16,711,000	35,234,353	7,100,000	18,083,743	11,711,837	5,150,000	560,681	$111,000,000

Source: CHVI Secretariat, December 2009

* Does not include an additional $495,850 provided by PHAC to support the Global HIV Vaccine Enterprise

Note: All figures for future spending of GoC departments were based on projections made for the original 5-year duration of the initiative. This table is being included for the purposes of the evaluation and will not be used to inform future spending by departments under the renewed CHVI.

3.0 Evaluation Methodology

This section will outline the rationale for the evaluation, the evaluation objectives, questions and methodology. It concludes by identifying the limitations to this evaluation.

PHAC programs, such as the CHVI, are subject to evaluation to demonstrate their successes and show results in accounting for (health) returns on the investments. The "Integrated Result-Based Management and Accountability Framework and Risk-based Audit Framework" (RMAF/RBAF) called for a mid-term (formative) evaluation prior to the completion of the third year of the Initiative (i.e. before March 2010). The purpose of this evaluation was "to assess how effectively the initiative is being implemented and whether adjustments are necessary."[13] The formative evaluation results were also expected to serve "as baseline data for the final summative evaluation."[14]

The Request for Proposals (RFP) specified that the results of the evaluation would serve three major purposes:

- Provide a preliminary assessment of the progress made in the first two years of implementation – how well the CHVI is contributing to/advancing discovery and social research; clinical trial capacity building and networks; policy, regulatory and community and social dimensions, partnerships, committees, and knowledge sharing will be examined;
- Contribute to better decision-making around how best to deliver the CHVI and provide strategies for continuous improvement;
- Assess the continued relevance of the CHVI and the projects it supports, providing objective information on whether the projects funded and the program as a whole make sense in terms of the needs and priorities the program is intended to address. This examination will assist with decisions on the program's future (key strategic directions, scope and allocation of resources, program priorities) and help ensure adequacy of response to public policy objectives.[15]

[13] Request for Proposal, Statement of Work
[14] Ibid.
[15] Ibid.

3.1 Evaluation Objectives

The objective of this formative evaluation was to assess the progress of the CHVI in the first two years of implementation and determine if changes are required to the design, delivery and direction of the activities.

The specific evaluation questions identified in the RFP for this evaluation were:

Implementation Progress

1. Is funding used fully, effectively and in keeping with plans and authorities?
2. What activities have been funded?
3. What client groups and organizations have received funding?
4. What research areas and what research priorities have received funding?
5. What delivery mechanisms have been used?
6. Is the program being delivered/ implemented as it was designed?
7. Is the governance structure effective?
8. Are collaborative arrangements between departments/ agencies/ Gates foundation effective?
9. Are there areas of duplication?

Achievement of Early Program Results

10. What progress has been made toward achievement of results?
11. What effect is the program having on beneficiaries?
12. Any unexpected results, whether positive or negative?
13. Is there a performance measurement system in place that involves all participating departments?

Role of CHVI and Ongoing Relevancy

14. What is required in the current HIV vaccine environment?
15. Consistency with Branch and partner organizations (other Government of Canada) mandate, objectives and priorities
16. Consistency with needs and priorities of primary beneficiaries and constituencies

Promising Practices and Lessons Learned

17. Would the CHVI benefit from a reallocation of funding and a change of emphasis between activities?
18. What worked well in the delivery of the research and community initiatives

programs?
19. What were some of the challenges in the community initiatives program?
20. What worked well in the pilot scale manufacturing facility component?
21. What were some of the challenges in the pilot scale manufacturing facility component?
22. Is CHVI linking well with key stakeholders involved in the HIV vaccine field?
23. Is CHVI linking well with key stakeholders involved in other areas of the HIV prevention technology field?
24. Are there ways to improve program delivery from either an effectiveness or efficiency perspective?

However, at the outset of the evaluation, it was clear that it would not be possible to address some proposed questions. Given the delays in the implementation of some CHVI components, it was suggested that these questions be excluded from this formative evaluation, but be addressed in a later evaluation. This was agreed to by the CHVI Secretariat and reflected in the revised evaluation matrix. As a result, the following questions were excluded from the evaluation:

11. What effect is the program having on beneficiaries?
12. Any unexpected results, whether positive or negative?
18. What worked well in the delivery of the research and community initiatives programs?
21. What were some of the challenges in the pilot scale manufacturing facility component?

A table in Appendix B shows the linkages between the evaluation findings within the report and the evaluation questions.

3.2 Evaluation Methodology

The methodology for this evaluation was primarily qualitative and included two sources of information – documents and key informants.

Document Review

The team conducted a review of key program documents, including among others:

- CHVI RMAF/RBAF;
- CHVI presentations, the CHVI web site, annual reports and other program background documents;
- CHVI financial information;
- Selected funding documents (announcements, Letters of Invitation, etc.); and
- Interdepartmental Steering Committee minutes.

The complete list of documents reviewed is provided in Appendix C.

A preliminary review was conducted to match the documentation available to the evaluation questions. Then selected documents were reviewed in detail to address specific evaluation questions. As additional documentation became available during the evaluation, it was reviewed by the evaluation team.

Key Informant Interviews

There were two groups of key informants – internal GoC stakeholders and external stakeholders. Interviews, using a structured interview guide, were conducted with both groups:

- In-person or telephone interviews with 20 internal stakeholders from the PHAC CHVI Secretariat and all participating GoC departments (CIDA, IC, CIHR, PHAC, HC). These interviews were conducted in June and July 2009; and
- Telephone interviews with 20 international and domestic external stakeholders with expertise relevant to specific CHVI domains. Interviewees included representatives from international organizations with an interest in HIV vaccine development as well as knowledge in specific issues related to the development of HIV vaccines in and for LMICs; representatives from domestic HIV/AIDS non-governmental organizations (NGOs); domestic HIV/AIDS researchers; experts on pilot scale vaccine manufacturing facilities; and representatives from the private sector (biomedical industry). These interviews were conducted in July and early August 2009.

Details of the key informant interview methodology are found in Appendices D to F:

- Appendix D: a summary of the key informants interviewed;
- Appendix E: internal stakeholder interview guide; and
- Appendix F: external stakeholder interview guide.

3.3 Limitations of the Evaluation

As with any evaluation, there are limitations on the interpretation of the evaluation findings that arise from the evaluation methodologies. Given the stage of CHVI implementation, the heavy reliance on qualitative information and the varied nature of the key informant respondents, many findings of this evaluation are based on a narrow field of interview responses. This limitation was somewhat mitigated by the use of documents to substantiate the findings from the key informant interviews.

Reliance on Qualitative Information

The original design of this formative evaluation included a survey of beneficiaries to examine early impacts of the Initiative. However, it became clear, given the delays in implementation across all components, that a survey of beneficiaries to assess early impacts would be premature. As a result, the evaluation focused on CHVI program activities and processes, rather than the measurement of results. Given that there are different external stakeholders for each CHVI component, it was decided that the most effective way to explore process issues with a diverse group of stakeholders was through key informant interviews. Although these were conducted using structured interview guides, there were no predetermined indicators for certain key concepts in the evaluation issues (e.g. "collaboration arrangements") and key informants defined their own expectations with respect to these concepts. As a result, it is possible that respondents had different ways of interpreting the concept and that the information collected is not consistent across all respondents.

Further, as a result of implementation delays, selection processes for some grants were still ongoing at the time of the evaluation. As a result, the evaluation team was not able to address the evaluation question related to the application processes. The evaluation findings thus rely, in some cases, on information from respondents with only general, second-hand knowledge of the application processes for specific grants.

In addition, since it was not possible to assess early impacts, this formative evaluation will not be able to provide the baseline data required for the next CHVI evaluation.

Limited Knowledge of Respondents

The evaluation team interviewed a variety of respondents with diverse expert knowledge of the CHVI components. Given the nature of the Initiative, with its diverse components, it was difficult for the evaluation team to interview stakeholders, other than a few internal stakeholders, who had sufficient knowledge of the Initiative as a whole. Since it was difficult for the evaluation team to find a large group of respondents who had experience with each aspect of the CHVI components, the team often had to rely on a limited number of responses to specific evaluation questions to develop the evaluation findings. This limited the team's analysis of specific components and results in somewhat fragmented views of the Initiative, as a whole. The team attempted to confirm the different perceptions of CHVI stakeholders by relying on documents, where available, or confirm early findings with later interviews (also where this was feasible).

Limited Access to Key Informant Interview Respondents

Key informants for the evaluation were identified by the CHVI Secretariat on the basis of those who had the most knowledge of the Initiative. The evaluation team was given a list of potential participants to contact rather than creating this list in cooperation with CHVI and key informants. This was an issue when key informants identified other external stakeholders with whom they felt the evaluation team should speak but were not on the list chosen by CHVI Secretariat. In addition, some potential participants declined to be interviewed.

This may have affected the detail reflected in evaluation results since, as noted above, a limited number of respondents could comment on aspects of each component. As follow-up interviews were not conducted, when suggested by other respondents, this may have limited the range of perspectives identified to the evaluation team but, more likely, limited the level of detail available to substantiate the views on some issues.

4.0 Evaluation Findings

This section presents the overall evaluation findings with respect to:

- The relevance of the Initiative to global efforts to develop an HIV vaccine, the relevance to Canada's domestic and international priorities and the relevance of the design of the Initiative;
- The progress made to date on each component, as well as any component results;
- The effectiveness of the collaboration with stakeholders; and
- The governance structure and performance measurement.

4.1 Relevance of the CHVI

The following section outlines CHVI's relevance as a Canadian initiative to contribute to the global effort toward an HIV vaccine, its relevance to Canada's domestic and international priorities and its design as a horizontal initiative.

4.1.1 Relevance of Supporting a Global HIV Vaccine Initiative

Respondents consistently had positive views about the relevance of the CHVI to the global efforts to develop an HIV vaccine and the need for an HIV vaccine initiative in Canada. The Initiative is well aligned with global priorities and ensures that Canada participates in the global effort to develop a vaccine. Key informants also added that the CHVI is well aligned with the Global HIV Vaccine Enterprise's 2005 SSP.

Canada's participation in the global HIV vaccine efforts was considered, by most respondents, as well aligned with Canada's relative strengths, such as having:

- An advantage in discovery research because of strong health research capacity and a history of innovation. However, this may have been hampered by the recent departure of a key HIV vaccine researcher and his team for the United States;
- Strong research capacity with respect to the social and policy dimensions and international expertise;
- Leading pharmaceutical manufacturers;
- Recognized expertise in regulatory issues; and
- Expertise in clinical trial capacity building.

However, concern was expressed from organizations in the field of HIV prevention regarding the limited amount of funding for research on HIV prevention technologies other than vaccines. Though CHVI was set up to focus only on HIV vaccines, others in the HIV prevention field question whether the CHVI should not be better linked to other prevention technologies, such as microbicides. As the field of preventative technology evolves, some experts in the field of HIV prevention around the world are looking at conducting trials focused on combining two or more prevention technologies to increase effectiveness. This approach is being reinforced by organizations advocating for combining different prevention technologies in a search for effective prevention (e.g. UNAIDS, Europrise's European Vaccines and Microbicides Enterprise, etc.).[16] It is possible that, in the near future, HIV prevention trials will combine two or more prevention technologies, such as a vaccine, microbicides and anti-viral medications. The mapping of all prevention technologies is currently being pursued within the context of the CHVI (see Section 3.4.4), which further enhances the relevance of the Initiative to global HIV prevention.

Another point of concern relates to the changing landscape of HIV vaccine research since the 2007 announcement of the CHVI, raising issues regarding the ability of multi-year initiatives to remain responsive and relevant to global priorities. Notable changes include the failure of some very prominent and promising vaccine candidates and changes to the HIV vaccine manufacturing requirements[17] – both of which have a direct impact on the vision of CHVI. Stakeholders questioned the emphasis being put on a pilot manufacturing facility, given these changes in the vaccine environment. They suggested that it was now more important to continue with basic research and address the regulatory framework for vaccine trials.

Changes in the environment for HIV vaccine research have had a global impact and the Global Enterprise's SPP is being revised to reflect the current environment. This raises important concerns about the CHVI's ability to remain responsive to changes and meet expectations of such an initiative in a global network that is constantly evolving. This highlights the inherent difficulties of multi-year initiatives to remain

[16] "UNAIDS promotes combination HIV prevention towards universal access goals", UNAIDS website http://www.unaids.org/en/KnowledgeCentre/Resources/PressCentre/PressReleases/2009/20090318_ComprehensivePrevention.asp (Accessed 20 January 2010). The purposed of the Europrise project is "is to bring together EU scientists from the microbicide and vaccine fields to embrace a coordinated approach to HIV-1 infection prevention research. Partners in the Europrise consortium represent 13 projects funded by the European Commission from the sixth Framework Programme as well as four projects funded by the Gates Foundation." http://ec.europa.eu/research/health/infectious-diseases/poverty-diseases/projects/132_en.htm (Accessed 3 April 2010)

[17] A stakeholder interview suggested that it is now possible for laboratories to produce internally some of their own vaccine candidates for Phase I and II trials or to use a series of smaller laboratories in the public sector.

relevant both globally and domestically.

4.1.2 Relevance to Canada's Domestic and Global Programming

The Initiative is relevant to both Canada's domestic and international programming. Domestically, the Initiative is consistent with other Canadian HIV/AIDS activities and Canada's support for building a world-class health-related research environment, including, particularly, vaccine research and development.
The CHVI built on, and is aligned with, other HIV-related programs, such as:

- PHAC's Federal Initiative to Address HIV/AIDS in Canada, which supports both prevention and mitigation activities;
- Vaccine-related research being carried out by CIHR; and
- Multi-stakeholder policy dialogues on vaccine-related issues being carried out by PHAC.

The Initiative is also consistent with other vaccine-related activities that are not HIV-related, but contribute to developing Canada's domestic capacity in vaccine development, including:

- The establishment, in 2004, of the National Microbiology Laboratory (PHAC), which is responsible for the identification, control and prevention of infectious diseases; and
- Support for the University of Saskatchewan's International Vaccine Centre, with a mandate to develop vaccines to protect people and animals from diseases such as avian influenza or tuberculosis.

Internationally, the Initiative is consistent with Canada's other activities to contribute to the global fight against HIV/AIDS, which focus on advancing effective, evidence-based HIV prevention, including linking HIV/AIDS with education and the development of new preventive technologies; promoting gender equality and women's empowerment to address the feminization of HIV/AIDS; strengthening health systems in developing countries to ensure equitable access to essential care, treatment and support for all those who need it; and promoting the rights of children and protecting and supporting those children infected and affected by HIV/AIDS. This includes:

- Canada's past support for the International AIDS Vaccine Initiative; and
- IDRC's GHRI HIV/AIDS Prevention Trial Capacity Building (Phase I) grants for

capacity building in Africa. Phase II of this work is now part of the CHVI.

4.1.3 Relevance of CHVI Design: Horizontal Initiative and Components

The creation of the CHVI as a horizontal initiative allowed the GoC to enhance programming collaboration among different departments/agencies to work together in the area of HIV vaccines. By combining limited funds and expertise in all relevant departments and agencies, the CHVI could allow Canada to become a more prominent player in the global arena. This collaboration would not only allow Canada to have more weight globally but also support strategically concerted efforts from different agencies and departments toward key objectives identified globally.

At the time the RMAF/RBAF was drafted, the CHVI was consistent with the Program Activity Architectures (PAAs) for all participating departments/agencies, as outlined in the RMAF/RBAF:

- ***PHAC***: The CHVI contributes to healthier Canadians through disease prevention and control and strengthening public health capacity;
- ***HC***: The CHVI contributes to HC's strategic outcome of healthy Canadians through a strengthened knowledge base to address health and health care priorities and access to safe and effective health products;
- ***CIHR***: The CHVI contributes to three strategic outcomes: outstanding research, outstanding researchers in innovative environments and transforming health research into action;
- ***IC***: The CHVI contributes to its strategic outcome for an innovative and knowledge-based economy; and
- ***CIDA***: The CHVI contributes to immediate outcome and output results statements: enhanced capacity and effectiveness of multilateral institutions and Canadian/international organizations in achieving development goals and strengthened partnerships with multilateral Institutions and Canadian/international organizations.[18]

While the RMAF/RBAF reflects the theoretical links between the CHVI activities and the mandates of the participating departments/agencies, a review of the Initiative design, as laid out in the RMAF/RBAF, found that the relationships among the different CHVI components and how the departments/ agencies were expected to

[18] RMAF/RBAF, p. 7 – 9

work together to achieve the overall CHVI objectives was not clearly reflected in the logic model (see Appendix A). This gap in the program design could also help explain the reported lack of collaboration among different departments/agencies involved in relatively separate components. This was a potential risk identified in the RMAF/RBAF that was to be mitigated by building on the knowledge gained in managing similar horizontal initiatives (e.g. the Federal Initiative on HIV/AIDS).[19] However, it appears that the CHVI was perceived as being more complex than other initiatives, thus limiting the relevance of the lessons from these other initiatives.

Conclusion: The CHVI is well aligned with global priorities and, specifically with the Global HIV Vaccine Enterprise's 2005 Scientific Strategic Plan. As such, it provides the GoC with a mechanism to contribute to the well-accepted global efforts to develop an HIV vaccine. External stakeholders did question the balance among the CHVI components, noting the importance of continuing with basic research and addressing the regulatory framework for vaccine trials. In addition, the creation of the CHVI as a horizontal initiative set up the GoC to be able to integrate funding from different departments/agencies and create synergies among the various partners. The CHVI components are also well aligned with Canada's relative strengths in the HIV vaccine field and are consistent with the Program Activity Architectures of the participating departments/agencies. However, the Initiative design does not adequately reflect the relationships among the components and the expected relationships and collaboration among participating departments/agencies.

4.2 Evaluation Findings by Component

This section presents evaluation findings that are specific to each of the four CHVI program components. Each section outlines the key findings. Since there have been substantial delays in the implementation of all components, the findings reflect few results and focus primarily on the process of implementation of the components.

Before discussing the findings by component, it is important to note that the first year of funding (2007/08) was intended to be a development year. Although the Initiative was announced publically in February 2007, financial authorities were not approved until June 2007. Even then, the authority to move forward only came in December 2007, after a delay of eight months to resolve issues associated with the reallocation of funding from the Federal Initiative for HIV/AIDS to CHVI. During the remainder of the development year, the focus of activities was on establishing a consultation

[19] Ibid, p. 41

process with external stakeholders, culminating in a public consultation which took place in February 2008 (see Section 3.2.4). This then became the start date for most activities within the specific components.

4.2.1 Discovery and Social Research

This component was seen as very important by the majority of respondents. In light of the failure of promising HIV vaccine candidates in the fall of 2007, most external stakeholders agree that it is important to put renewed emphasis on basic research and discovery. The opinions were mixed concerning the importance of social research at this stage of the HIV vaccine discovery process.

Thirteen grants have been awarded under this component – eight Catalyst Grants and five Operating Grants. Applicants for five Emerging Team grants have been invited to submit full applications (For details of the awards, see Appendix H). While there is potential for duplication in sources of funding for discovery research, it was considered appropriate in order to follow the greatest number of leads to discover new vaccines. However, the inclusion of CIHR as a partner in the CHVI ensured that Canadian duplication of funding would be unlikely. CIHR works closely with Social Sciences and Humanities Research Council and the Natural Sciences and Engineering Research Council to ensure that all health research applications get reviewed by CIHR and ensure that HIV vaccine research applications would automatically get forwarded to the appropriate area.

This component has experienced delays in implementation of some grants. Exhibit 4.1 summarizes the timeframes for the Discovery and Social Research grants.

Exhibit 4.1: Timeframes for Discovery and Social Research Grants

Grant	Expected launch	Actual launch	Results
Catalyst Grants	Grant program originally suggested at February 2008 consultation	August 2008	7 applications received; 5 funded
		December 2008	4 applications, 3 funded
		July 2009	Awaiting results. Due March 2010
Operating Grants	2008/09	June 2008	7 applications received; 2 funded and additional 3 funded through CIHR's regular funding streams
		December 2008	10 applications received; 3 funded
Emerging Team Grants	2007/08	May 2009	6 Letters of Intent; 5 to develop applications by

Grant	Expected launch	Actual launch	Results
			March 2010
Large Team Grants	2008/09	Discussed at October 2008 international conference but not yet launched. Expected to be launched in spring 2010	n/a

Source: CHVI Secretariat, November 2009, updated by partners

The first Catalyst and Operating Grants were launched within four to six months following the stakeholder consultations in February 2008 in tandem with CIHR's regular launch cycles. This contributed to ensuring maximum engagement by the health research community.

The Emerging Team Grant funding opportunity was launched in May 2009 to the fill the void created by a delay in launching the Large Team Grants. Initially, the launch of the Large Team grants was delayed to allow for discussion specifically on these grants at the Global HIV Vaccine Enterprise's AIDS Vaccine 2008 Conference, held in Cape Town in October 2008. During the conference, a workshop to review the draft Request for Applications (RFA) for the Large Team grants was held. This delay was compounded by the requirement for an interdepartmental transfer of funds between CIDA and CIHR. It is now anticipated the agreement will be finalized in early 2010 and the Large Team Grant RFAs will be launched shortly thereafter. If application process is launched in the spring of 2010, two years will have passed since the announcement of the Initiative.

Box 4.1: Delays from the Stakeholder Perspective

On 20 February 2007, the Prime Minister and Bill Gates of the Gates Foundation announced Canada's new funding for HIV vaccine research. The financial authorities for the new Initiative were approved in June 2007. One year after the announcement of the Initiative (February 2008) – a year that was defined by the Initiative as a development year – a reportedly very successful consultation with external stakeholders was held and the CHVI web site was launched. Although the first CHVI grant program for Discovery and Social Research (Operating Grants) was launched in June 2008, this was sixteen months after the high profile announcement of the Initiative. Since external stakeholders cannot be aware of the internal development activities being undertaken to put funding in place and set up the grants and contribution arrangements, there appears, from a stakeholder perspective, to have been a long gap between the announcement and any outputs of the Initiative.

While the delays can often be attributed to understandable checks and balances within the GoC, these challenges are not often visible or comprehensible to the broader stakeholder community. (See Box 4.1 for the community perspective on the timeframes.)

Many external stakeholders (and some internal stakeholders) report that these delays are undermining CHVI's profile in the research community. Some researchers report that these delays are not only undermining CHVI's credibility within the Canadian research community, but their profile in the global arena, since

the delays in these grants have overshadowed the timeliness of other funding streams (e.g. the Catalyst and Operating Grants). In addition, stakeholders have identified challenges in accessing public information about the progress on these grants.[20]

Some respondents felt that fewer researchers than expected applied for and received Catalyst Grants. The response was reportedly low because of the targeted nature of the funding and the relatively small size of the HIV vaccine research community. Some respondents indicated that the limited uptake could have been due to the lack of readiness in the research community to conduct research in the field.

Respondents had mixed views on the application process for the various Discovery and Social Research grants:

- ***Catalyst Grants***: Most respondents felt that the five-page application was simple and encouraged applications but others questioned the need for even a five-page application when the Bill & Melinda Gates Foundation only required a two-page application for its discovery grants.
- ***Operating Grants*** and ***Emerging Team Grants***: Respondents indicated that these are managed as other CIHR grants and researchers are familiar with the format. As a result, respondents had very few comments, suggesting that the application process worked well. Some did comment on the challenge of creating partnerships for the Emerging Team grants.

Some respondents anticipated challenges in applying for the ***Large Team Grants*** because of the inherent difficulties of putting together a large team required for these grants. Some respondents struggled to create new partnerships with researchers in LMICs, who often have limited capacity to access or use advanced biomedical research; while others indicated that they had already established these partnerships and were well-positioned to respond when the application announcement was made.

[20] Some components of the CHVI website have not been updated for at least a year.

4.2.2 Clinical Trial Capacity Building and Networks

This component was identified as critical by most stakeholders, as building capacity takes years and this capacity will be required immediately when new vaccine candidates move to the clinical phases. Some European organizations are currently building and maintaining capacity for clinical trials in LMICs, but respondents report that the need for such capacity currently exceeds what has already been achieved.

Exhibit 4.2: Timeframes for Clinical Trial Capacity Building and Networks Component

Activity	Expected completion date	Actual completion date
Consultation with stakeholders	2007/08	February 2008
Agreement signed between CIDA and IDRC for transfer of $6M		January 2009
First call for Letters of Intent	2007/08	July 2009
Letters of Intent due		September 2009
Expected release of results/grant awards	2008/09	March 2010

Source: CHVI Secretariat, November 2009

There have been significant delays in the implementation of this component. As shown in Exhibit 4.2, if the start date of the work on the component was the consultations with stakeholders in February 2008, it is expected that it will be twenty-five months between this start and the expected release of the funding results in March 2010. [21] In addition, this will only result in the allocation of $6M of the $16M that CIDA committed for this component. As of August 2009 when data collection was being completed, an agreement had yet to be put in place for the remaining $10M between CIDA and IDRC.

The Letter of Intent for the Clinical Trial Capacity Building Grants indicated that these grants would be profiled over four years. However, the application process was launched in July 2009, the results are expected in March 2010 and the spending authority extends only until March 2013. There is, as a result, a timing challenge. Capacity building takes time and, since there will not be four years over which the work can take place, the achievement of the expected results may be limited.

[21] The $6M has already been announced by CIDA on World AIDS Day on 1 December 2006. This money was then re-profiled for the CHVI.

4.2.3 Pilot Scale Manufacturing Capacity for Clinical Trial Lots

This component has been the major focus of the CHVI Secretariat's time so far (reportedly between 33 and 50% of its time). The majority of respondents felt that the need for this facility should have been reassessed after the failure of a promising HIV vaccine candidate in the fall of 2007. Some stakeholders would have preferred that the CHVI hold public consultations after the failure of the clinical trials was announced. A key principle for the CHVI was that there be multi-sectoral collaboration and engagement. Given the importance of the failure of the vaccine trials on the efforts to develop an HIV vaccine, these respondents felt that this would have been an important time for the engagement of stakeholders to discuss the way forward. However, the public consultations held shortly after the failure of the vaccine trials (in February 2008) focused solely on the CHVI funding programs. Given the high profile announcement of the CHVI, with a particular focus on the pilot scale manufacturing component and the Bill & Melinda Gates Foundation's support for it, it did not seem appropriate to open the question of the rationale for this component at that time. The majority of external stakeholders and some internal stakeholders stated, at the time of this evaluation, that a higher priority should temporarily be given to basic research until more HIV vaccines candidates are in the pipeline.

Those who supported the continuance of this component noted that there is no comparable non-profit facility in the world. A non-profit pilot scale manufacturing facility exists in the United States, but this facility is only available for scientists associated with National Institutes of Health's Vaccine Research Center. Given that the proposed facility would focus on ensuring global access for vaccine researchers and it would have had the capacity to be used to produce other vaccines, some respondents thought that it was a worthwhile component.

During implementation, this process faced important delays (see Exhibit 4.3). The call for Letters of Intent was launched very soon after the stakeholder consultations in February 2008. However, as can be seen in Exhibit 4.3, significant delays first appeared in the process during the review of the Letters of Intent, which occurred during the summer of 2008. The second point of delay occurred during the review of the full applications. The delays can be attributed to challenges with interdepartmental approval processes, administrative issues associated with the expert working group (e.g. addressing conflict of interest issues, level of effort required) and delays caused

by summer holidays and the federal election.[22] There was reportedly a need to ask for clarification from some applicants on the financial components of the application. This also contributed to the delays in the decision-making processes. Then, the CHVI Secretariat informed the evaluation team that, in late July 2009, the GoC and the Bill & Melinda Gates Foundation made a recommendation to not proceed with the facility.[23]

Exhibit 4.3: Timeline for Pilot Scale Manufacturing Capacity of Trial Lots Component

Activity	Expected completion date	Actual completion date
Consultations with stakeholders	2007/08	February 2008
Call for Letters of Intent	March 2008	April 2008
Receipt of Letters of Intent	May 2008	June 2008
Successful LOI applicants invited to submit full applications	June 2008	November 2008
Receipt of full applications	October 2008	March 2009
Funding recommendation	2008/09	July 2009

Source: CHVI Secretariat, December 2009

Most respondents commented that the review process was well coordinated by the CHVI Secretariat and that they were able to gather successfully the appropriate expertise from the vaccine field while ensuring that reviewers chosen for the tasks had no conflict of interests (although this contributed to delays in the process). The application process was described as well-outlined, clear and thorough and the rating of the applications was easy to understand for persons without vaccine manufacturing expertise. However, in hindsight, some respondents reported that the Letter of Intent may not have been necessary and CHVI could have moved directly to the request for applications. However, given the newness of this process and lack of information about the number of potential applicants, it was considered to be safer to start with a less demanding and expensive process to gauge interest.

Although it has now been recommended that the component not move forward as planned, respondents noted that the engagement of the Bill & Melinda Gates Foundation in this component to date was seen as a positive element of the Initiative. In fact, the collaboration between CHVI, the GoC and the Bill & Melinda Gates Foundation over the past three years has reportedly contributed to increasing the GoC's credibility as a significant partner in the fight against HIV/AIDS, has facilitated relationships with international players and has leveraged Canadian

[22] No contact was made with any applicants during the election.
[23] On 19 February 2010, the decision not to proceed with the facility was announced jointly by the GoC and the Gates Foundation. See http://www.chvi-icvv.gc.ca/index-eng.html Accessed April 2010

expertise in the HIV/AIDS field.

While respondents generally felt that private/public partnerships are necessary in these types of initiatives, the CHVI also faced challenges in engaging the private sector in partnerships for this component. The CHVI manufacturing component was at a stage where it was oriented mostly towards non-profit organizations and academic researchers. As a result, there was little to attract the private sector to the Initiative before a successful bid for the facility was accepted. However, since the launch of this component, a concept paper has been developed that outlines how public private partnerships could be structured to engage effectively all partners, especially the private sector, to achieve the aims of the CHVI (see Section 4.2.4). The high-level ideas regarding structure, governance and operational management will assist the CHVI in comprehending this complex issue and determining the process to take in developing public-private partnerships in the future.

Potential challenges were also identified with the sustainability of the manufacturing facility. Respondents questioned the balance between the viability of the facility and serving researchers globally, including in LMICs. This led to questions regarding the objectives of the facility and highlighted tensions between the domestic and international objectives of the partner departments/ agencies.

The recommendation by the GoC and the Bill & Melinda Gates Foundation to not proceed with the establishment of a manufacturing facility occurred after the completion of the data collection for this evaluation. As a result, the evaluation team did not have the opportunity to assess the impact of this recommendation, on either the participants or the departments/agencies.

4.2.4 Policy and Regulatory Issues, Community and Social Dimensions

This component includes a number of different activities, including policy development, the development of a regulatory framework and addressing legal, ethical and human rights dimensions of HIV vaccines.

CHVI Policy Activities

Consultations on the CHVI policy agenda were completed in early 2009/10 and a draft deck presented to the program-level Interdepartmental Committee in the summer of 2009. Although work has begun on a regulatory forum, further work on the policy

agenda has been delayed because of the uncertainty surrounding the Pilot Scale Manufacturing component and need for the Interdepartmental Steering Committee to determine the impact of this uncertainty on the various CHVI components. Respondents have reported a need for additional work on regulatory issues. One respondent provided the specific example of a potential issue with researchers developing products that would not be approved by a regulatory body for clinical trials on humans. New researchers may be unaware of the requirements for testing on humans, compared to animals.

The CHVI, through HC, funded two grants to strengthen the ethical-legal framework for HIV vaccine trials and support dissemination and translation to promote participatory practice guidelines for biomedical HIV prevention trials (see details in Appendices G and H). These were completed in a timely manner in 2007/08 and the results presented in a satellite session sponsored/hosted by HC and PHAC at the Canadian Association of HIV Research Conference 2008 in Vancouver. Another proposal is being considered to contribute to building sustainable regulatory capacity in LMICs. Respondents reported a need to share information with researchers on key regulatory issues (e.g. intellectual property, regulations limiting the use of certain cell types on humans, etc.).

Discussions on stakeholder engagement began in late 2007 and a partnership development and stakeholder engagement framework, which defined how various parties will work together, was approved by the Interdepartmental Steering Committee in January 2009. The work on this framework during 2008 led to the need for a research paper on public-private partnerships, which was finalized in September 2009. As with the grant activities of the various CHVI component, the process of developing this paper was also subject to considerable delays (see Box 4.2).

A literature review on the synergies between new HIV vaccines and prevention technologies has been conducted to assist the CHVI in defining possible linkages with other prevention technologies, such as microbicides and pre-exposure prophylaxis. It focused on exploring and recognizing opportunities for resource-sharing, collaboration and knowledge exchange.[24] A new contract is under development for mapping these other prevention technologies.

[24] "Literature Review: Potential Synergies Between HIV Vaccines, Microbicides and Pre-Exposure Prophylaxis: Final Report", prepared for the Public Health Agency of Canada by San Patten and Associates, March 31, 2009, p. 3

Community Initiatives Fund

The key programming activity within this component has been the CI Fund. As noted in the invitation to submit applications, the main goal of the Fund is to strengthen Canada's contribution to global HIV vaccine-related development and community engagement efforts. Two projects have been funded under the CI Fund.

Box 4.2: Timeline for Public-Private Partnership Paper

The initial proposal for the development of the public-private partnership (PPP) paper was submitted in February 2008. The Policy Working Group of the program-level Interdepartmental Committee discussed the proposal from February to June 2008, to ensure that the work did not duplicate information already in the public domain. However, ultimately, no pertinent papers were identified that addressed PPPs from the perspective of the CHVI. In October 2008, the requirements for the paper were revisited with IC and PHAC interdepartmental representatives and revisions were made to the scope of the project. In January 2009 the consultant re-submitted a proposal, which was approved by the Interdepartmental Committee. The contract was signed in February 2009 and the paper was completed in September 2009 – nineteen months after the first proposal. PPPs have been identified as a key component in the draft policy agenda.

Duplication of funding, particularly with the Federal Initiative to Address HIV/AIDS in Canada, was avoided by having PHAC and HC staff review applications to both programs. In addition, if applicants apply to the Federal Initiative for vaccine-related funding programs, they are made aware of the CHVI funding stream. Also, duplication was avoided by partnership with international organizations to ensure coordinated and complementary funding for recipients.

Respondents also highlighted the importance of research on community engagement. There is a risk that there may be more scepticism in the community about HIV vaccines, in light of the failure of important HIV vaccine clinical trials. This highlights the continued need to engage communities in the global effort to develop a vaccine.

Exhibit 4.4: Timeline for Community Initiative Fund

Activity	Expected completion date	Actual completion date
Consultations with stakeholders	2007/08	February 2008
Draft Invitation to Submit Applications		May 2008
Public online consultation on draft ISA		August 2008
Interdepartmental approval and launch of first ISA	2007/08	January 2009
Receipt of applications		March 2009
Approval of first round of projects	2008/09	December 2009

Source: CHVI Secretariat, December 2009

As with the other components, there were delays and challenges in the

implementation of these contribution agreements (see Exhibit 4.4). The CI Fund was launched in January 2009, but only two applications were received from community organizations as a result of this first call for proposals. This limited response to the call for proposals was attributed, by internal stakeholders, to a number of factors:

- The commitment made at the February 2008 consultation to hold public consultations on the draft Invitation to Submit Applications (ISA). While this reportedly provided more clarity on roles and responsibilities for the funding, it did add to the timeframes.
- The deadline for applications was in March – a particularly busy time of year for community organizations seeking federal funding from other programs available to NGOs (for example, the Federal Initiative).
- The capacity of NGOs may also have been stretched because of year-end pressures to complete their deliverables for existing projects before the end of the federal government's fiscal year;
- There may be limited capacity to address HIV vaccine issues (or the NGOs may not have recognized the fit between their mandates and objectives of the Fund); and
- The call was initially not restrictive to allow organizations to shape their own projects. However, this led to organizations not seeing clearly how they could contribute to this component of the Initiative. The CHVI is now working closely with community organizations to develop further their interest in this aspect of community engagement.

Conclusion: The first year of the CHVI was considered to be a development year. Although the Initiative was announced in February 2007, it was December 2007 before the financial authorities were approved and the financial transfers were completed. At that date, the Initiative could move forward. During that period the CHVI Secretariat established a consultation process with external stakeholders, which ended with a public consultation in February 2008. This then became the start date for most activities within the specific components.

The CHVI is a complex, multi-departmental initiative, requiring the engagement of not only five departments/agencies and the Bill & Melinda Gates Foundation, but also a wide group of other external stakeholders. With the exception of some policy work being done by the CHVI Secretariat, most of the Initiative's activities are implemented through the not-for-profit sector – notably the academic and research communities and HIV/AIDS NGOs. All four CHVI program components relied heavily on transfer payments, through grants or contributions,

with academics, researchers and NGOs. There were, at times, very significant delays in the launching of, and decision-making for, some of these transfer payments. These can be attributed to weaknesses in the collaboration across partner departments/agencies and the need to accommodate different decision-making processes in the various departments/ agencies.

While departments/agencies may be effectively coordinating their own processes, the internal efforts that have been underway have not been transparent to the broader, external community. Significant time has elapsed from the announcement of the Initiative, the public consultations and the launch of some of the funding opportunities. As a result, there is considerable frustration within the HIV/AIDS community about the apparent lack of progress on Canada's contribution to the global efforts to develop an HIV vaccine. In addition, these delays have put into question the extent to which the CHVI can achieve the expected results within the remaining timeframe for the Initiative.

Not only have there been delays in the implementation of all components, but some components have also not experienced the expected results for their activities to date. The most obvious is the recommendation of the GoC and the Bill & Melinda Gates Foundation to not proceed with the Pilot Scale Manufacturing Facility component as planned. Also the Community Initiative Fund did not receive as many applications as expected. This limited response was attributed to limitations in the HIV community's engagement in vaccine research issues. PHAC has already adjusted its approach to working with HIV community organizations to strengthen their engagement in the Initiative by working with HIV/AIDS NGOs to help build their capacity to submit relevant proposals and encouraging them to participate in CHVI-related events.

Most internal and external stakeholders felt that there was a need to reassess the balance among the CHVI components – particularly the emphasis on the pilot scale manufacturing capacity for clinical trial lots component following the failure in the fall of 2007 of a promising HIV vaccine candidate. They felt that greater emphasis should have been put primarily on basic research and discovery as well as on regulatory issues. Both of these are critical to ensure global access.

4.3 Planning and Coordination

4.3.1 Communication and Collaboration with External Stakeholders

Communications

Overall the evaluation team received very positive feedback concerning CHVI's consultations on funding programs held in February 2008. About 80 domestic and international stakeholders from the public, private and non-governmental sectors participated in the consultation. The main objective was "to obtain input on CHVI funding programs designed to focus on the development of important program elements for those departments and agencies providing leadership to the CHVI."[25] Ideas identified in this consultation that were implemented included the policy mapping and work on identifying the linkages with other prevention technologies. In addition, a suggestion that draft Invitations to Submit Applications (ISA) be reviewed by potential applicants before the launch was implemented prior to the launch of the CI Fund. This allowed potential applicants to comment on the funding requirements.

Some respondents also mentioned the fact that the CHVI had been responsive to community needs by extending deadlines to reach out to more stakeholders during different requests for applications. However, they were divided on whether or not the extra reach justified the resulting delays.

In spite of these positive comments about the Initiative's outreach, a majority of external stakeholders identified challenges in the ongoing communication of the Initiative. They indicated that, in the past year, there had been few public announcements about the Initiative or information provided on progress in the implementation of the components. Little information was available on the CHVI website. It is obviously challenging for the Secretariat to identify public messages when there are delays in implementation, caused by internal GoC issues. Even when material was posted on the CHVI website, it was often not done in a timely fashion because of internal delays in approving and translating texts.

Some felt that, as a result of the limited communications, CHVI had lost some of its momentum – the perception was that the level of the government's engagement had fallen after the high level of enthusiasm generated by the public consultations in

[25] "Consultation on CHVI Funding Programs" February 10 – 12, 2008, p. 4

February 2008. A few respondents pointed out that the fact that sections of the CHVI website were out of date (some had not been updated in more than twelve months) was a reflection of a lack of focus on external communications.

The concerns of stakeholders differed – researchers felt that they were not given sufficient information on the status of grants and researchers and NGOs would have liked more consistent, regular information on the progress of the Initiative.

The current approach to CHVI communications is primarily reactive, partly because of the delays in some components. A CHVI Communication Strategy is currently in the process of being reviewed and approved, the main objectives of which are to:

- "Highlight Canada's lead role in international efforts to accelerate the development of a safe, effective, affordable and accessible HIV vaccine;
- Demonstrate that the Government of Canada is committed to supporting a comprehensive, long-term, collaborative global approach towards accelerating the pace of discovery of an HIV vaccine for global use;
- Demonstrate the progress of the CHVI to key national and international media, and key stakeholder groups; and
- Promote and maintain awareness of the CHVI throughout the duration of the initiative."[26]

Collaboration

Collaboration with the Bill & Melinda Gates Foundation on the CHVI was considered to be critical to both strengthening Canada's participation in the global efforts to develop an HIV vaccine and to enhancing Canada's credibility. The Foundation already has a high profile and a strong reputation and the CHVI benefits from an association with it.

On the other hand, a few internal stakeholders expressed concerns that the Bill & Melinda Gates Foundation's role was limited to the pilot scale manufacturing component. Some respondents felt it might have been more effective to leverage the technical expertise of the Foundation in all components. Although the interest of the Foundation was solely in the manufacturing component, it did provide input to the policy and regulatory issues component (e.g. through participating in, or providing inputs to, the 2008 funding consultations, CHVI policy agenda, public-private

[26] "Communications Strategy – Phase 1 Implementation: Work Plan: March-July 2009 (first draft)", p. 1

partnerships, and the satellite session in Mexico). In addition, at the request of the Foundation, a single point of contact with the Initiative was identified. This role was played by the Secretariat, which had informal teleconferences with Bill & Melinda Gates Foundation representatives to provide information on the progress of the implementation of CHVI components and solicit feedback from the Foundation. Respondents from some departments/agencies felt that this centralized too much the communications with the Foundation and wished for more access to the Foundation so that they would be able to leverage its expertise.

Collaboration on the CHVI was primarily invested with non-governmental organizations. The calls for proposals and funding arrangements related to CHVI activities, was for the most part, targeted towards the not-for-profit sector. The Initiative design included engagement of the private sector. Two CHVI principles speak to the importance of the private sector in this initiative:

- Strategic coordination and integration to focus Canadian public and private sector expertise to address the goals of the Global Enterprise; and
- Multi-sectoral collaboration and engagement, which included the private sector.

However, the engagement of the private sector was considered limited and many respondents reported that as a result, there was no evidence of strong links to the private sector in biomedical technologies. For industry representatives, the challenge was that they felt there was not a sufficient business perspective on the development of the manufacturing component. It is recognized that the private sector was directly involved in only one component (i.e. the Pilot Scale Manufacturing component); the others focused on university researchers and NGOs. Further, even in this component, bids had to be led by NGOs, which left limited room for engagement of the private sector.

4.3.2 Communication and Collaboration with Internal Stakeholders

Communications

The evaluation team received positive feedback from respondents concerning the communication activities between different departments/agencies and the Secretariat. Respondents noted that the role of the Secretariat had evolved to the point that it was providing more leadership to ensure progress of the Initiative (see Section 3.4.1). Issues of cross-component and departments/agencies in terms of objectives, mandates and approval processes are thought to be a major contributor to the delay in the implementation of CHVI.

Collaboration

The effectiveness of collaboration among stakeholders internal to the GoC was raised as a concern by some respondents. The lack of effectiveness was reportedly due to the limited capacity or engagement of some department/agencies, as well as challenges inherent in horizontal initiatives. Some of these challenges included working with departments/agencies with different mandates, priorities and programming requirements. In spite of the demonstrated links between the Initiative's components and the PAAs of the participating departments/agencies (see Section 3.1.2), some internal stakeholders reported different degrees of congruence between the objectives of the CHVI components and the mandate of their own department/agency. For example, not every government department has an HIV mandate and some departments/agencies have HIV prevention mandates, but not necessarily in a Canadian context or in the field of HIV vaccines. This was particularly evident in the Pilot Scale Manufacturing Facility component, since it was clear from the beginning that funds to be transferred by CIDA for this component could not be counted as Official Development Assistance (ODA). While CIDA's engagement in this component was within its mandate, it was not well aligned with the Agency's primary mandate, which is development assistance.

In addition, some departments/agencies had different requirements for program approval and different roles to play on the Initiative. These differences created tension within the horizontal initiative and sent mixed messages regarding the objectives and activities of CHVI to the external stakeholder community. For example, part of CIHR's role on the Initiative was to "bring critical expertise in peer review mechanisms and related professional support services to identify and fund eligible

HIV vaccines projects."[27] Its approach to awarding research grants, through a peer-review process, is globally accepted for academic research, yet it may not have met the expectations of other departments/agencies. It would, for example, be unusual for CIHR to require researchers to submit proposals that demonstrate collaboration with researchers in LMICs. Yet this is the approach that CIDA wanted to take with the Large Team Grants – an approach that is consistent with its role in the Initiative to "ensure that the goals of the CHVI promote the development and delivery of HIV vaccines that benefit the needs of the highly endemic HIV/AIDS countries in the developing world."[28]

PHAC and CIHR were the only partners to identify their full-time equivalent (FTE) human resource requirements for the implementation of the Initiative. Given the heavy workload associated with a horizontal initiative of this magnitude, it was found that most departments/agencies had not been adequately prepared. This lack of pre-assigned dedicated and consistent staff in departments/ agencies inhibited collaboration among the partners and contributed to the delays in some components.

This evaluation found that the opportunity to collaborate with other departments and across CHVI components was lacking, with most working independently. Given the initial design of this initiative to build on existing networks of key partners, no evidence was found that these networks were being utilized in the CHVI.

Conclusion: The views of the CHVI's communication with internal and external stakeholders were mixed. On the one hand, there were very positive assessments of the broad consultations on the funding programs with external stakeholders held in February 2008. On the other hand, external stakeholders were disappointed by the lack of communication or transparency on the progress and processes of various components. This concern has been compounded by the delays in the implementation of the Initiative and the challenge of the external community in accessing up-to-date information about the Initiative.

Internal interview respondents were generally positive about the internal coordination of the Initiative and noted particularly the extent to which the Secretariat had adapted its role to meet the needs of the interdepartmental committees. However, some challenges were reported due to the limited capacity or engagement of some department/ agencies as well as challenges inherent in horizontal initiatives, including the challenges of partnerships among departments/ agencies with different mandates, priorities and programming requirements.

[27] RMAF/RBAF, p. 12
[28] Ibid, p. 13

In spite of the demonstrated links between the Initiative's components and the PAAs of the participating departments/agencies, some internal stakeholders reported different degrees of congruence between the CHVI mandate and that of their own department/agency. As a result, there was little evidence of collaboration among participating departments/agencies beyond their specific component requirements. In addition, these departments/agencies have different programming requirements, which made joint decision-making challenging. The delays experienced by all four program components were, to some extent, attributable to the challenges of interdepartmental approval processes.

4.4 Governance and Performance Measurement

4.4.1 Governance

There are three key groups involved in the governance of the Initiative – the CHVI Secretariat, the Director Generals (DG) Interdepartmental Steering Committee and the Interdepartmental Committee (program level).

CHVI Secretariat/ Office of HIV Vaccines

The role of the CHVI Secretariat is to work in "close collaboration with participating departments/agencies to ensure a coordinated cohesive approach. The Secretariat will provide operational support and coordinate activities related to: the Steering Committee; the Advisory Committee; partnership and stakeholder engagement; and planning, monitoring, reporting and evaluation."[29]

The CHVI Secretariat was set up in PHAC at the outset of the Initiative and completed its staffing in the first year and a half. Some respondents view the Secretariat as being over-staffed and lacking the sufficient technical expertise to administer such a scientific initiative. In spite of the Secretariat's active engagement in the international HIV vaccine community (see Box 3.3), this gap has led to the lack of a clear

Box 3.3: Activities of the CHVI Secretariat

The CHVI Secretariat has been actively engaged in international HIV vaccine events. It organized a policy dialogue session in Mexico in August 2008. Three abstracts were submitted and accepted as poster presentations at the AIDS Vaccine 2009 Conference in Paris in October. The CHVI has also been invited to participate in a panel discussion hosted by the AIDS Vaccine Advocacy Coalition.

[29] Ibid, p. 10

connection between the Secretariat and vaccine researchers and has reportedly led to missed opportunities to promote Canadian researchers (as representatives of CHVI) on the international scene. Key informants noted that the field of HIV vaccines is a very technical and rapidly evolving field and that there was a need for more senior and/ or external scientific advisors to help guide the CHVI on technical issues. However, it is important to note that the Secretariat has made efforts to hire technical HIV vaccine experts, but has been unable to do so at the time of this evaluation.

As required, the role of the CHVI Secretariat responded to the need for more structure and centralization of information for the benefit of all the departments and agencies participating in the CHVI. As the Initiative progressed, the Secretariat took more of a leadership role to ensure progress. Though sceptical of the role of the Secretariat at first, most respondents expressed an even greater need for the CHVI Secretariat to act as a filter of information for participating departments and agencies to alleviate the administrative burden.

The work of the Secretariat is judged by most respondents as being effective. It is perceived as being organized, in spite of having to deal with a high volume of information, and as serving the interdepartmental and review committees well. It is also seen as being open to, and capable of, managing differing points of view as well as being diligent in managing any real or perceived conflicts of interests in the manufacturing component.

Interdepartmental Steering Committee

The DG-level Interdepartmental Steering Committee met as needed by teleconference but, given the schedules of the participants, was seldom able to hold in-person meetings. This was identified as a challenge and may have contributed to the lack of coordination between the participating departments/agencies. Respondents also questioned the balance and representativeness of the views being heard during Steering Committee meetings. Based on a review of meeting minutes, the evaluation team found that some DGs missed more than half the meetings or sent program-level representatives. This compounded the challenges of moving forward with interdepartmental approval processes.

Respondents were also critical of the fact that the Committee is not sufficiently proactive and does not focus enough on strategic issues. Some respondents felt that challenging strategic issues were often not discussed. This was confirmed by the

evaluation team's review of the Committee minutes.[30] The team found no record of discussions of the re-examination of the emphasis on the pilot scale manufacturing component. Yet, this issue was clearly identified, in the interviews with the different partner departments/agencies, as being a critical issue for the Initiative.

The Committee reflected due diligence by minimizing perceived conflicts of interest within the Initiative. Two members of the Committee, with affiliations to organizations applying for the facility funding, identified a potential conflict of interest with respect to the decision-making on the pilot scale manufacturing component and requested that they be replaced at meetings dealing with this component. As a result, a separate DG Steering Committee was formed, specifically for these consultations, with two other senior departmental representatives. Decision-making responsibility for this component was shared with the Bill & Melinda Gates Foundation. Discussions between the Government of Canada and the Bill & Melinda Gates Foundation were led by Canada's Chief Public Health Officer, with the participation of representatives from the CHVI participating departments/agencies.

Interdepartmental Committee (Program-level)

Respondents reported that the strength of this Committee was the frequency and length of regular meetings, which allowed for discussion of important issues and opportunities to participate in informational presentations from experts concerning the CHVI components to the Committee. Further, members of this Committee reported greater collaboration at this level than at the Steering Committee level. Some challenges identified by internal stakeholders were the heavy workload of staff from other departments/ agencies which limited the amount of time they could spend on the CHVI, a high level of turnover of staff and the ensuing loss of corporate memory, and a continued tendency to work in silos.

This Interdepartmental Committee also established working groups, some of which have been disbanded (e.g. the Policy Working Group) because of the duplication in membership between the Working Group and the Committee. Others meet as required (e.g. Clinical Trials Working Group and the Communications Working Group).

[30] Including the minutes of the separate DG committee set up to manage the pilot scale manufacturing facility component

4.4.2 Performance Measurement

An RMAF/RBAF was developed at the time of the TB Submission for the approval of the CHVI. The document profiles the Initiative and the strategies for monitoring and evaluating its implementation. This includes plans for performance measurement across all participating departments/agencies. The need for this formative evaluation was identified in the RMAF/RBAF and launched by the CHVI Secretariat.

However, a number of other activities called for in the RMAF/RBAF have not been implemented. For example, no shared database has been created to collect and store information to help evaluate CHVI activities. There are no processes in place to collect data to address the indicators identified in the RMAF/RBAF. While this is not a significant issue given the limited progress in implementation at this date, it will become more critical in the future and will affect the ability to conduct the next CHVI evaluation.

The RMAF/RBAF clearly outlines the links between the CHVI and the existing PAAs for participating departments/agencies. However, the CHVI logic model (see Appendix A) included in the RMAF is not sufficiently detailed to demonstrate the linkages and synergies between the program components. It does not identify the components and their specific expected outputs and outcomes. As the participating departments/ agencies tended to focus on their own specific components, a logic model which does not identify the specific components, made it more difficult for departments/agencies to identify how their activities are intended to contribute to those of their partners and create the necessary collaboration.

Conclusion: The governance mechanisms have been generally effective, although the Interdepartmental Steering Committee has not been sufficiently proactive and does not focus enough on strategic issues. PHAC and the Secretariat have achieved much in the first year and a half of the Initiative. The Secretariat has become fully staffed and its role has evolved based on the needs of the Initiative. However, a need still exists for technical capacity in the Secretariat. The Secretariat has taken on more leadership and has learned some lessons with respect to the management of the Initiative. It has adapted its internal communication strategy to better meet the needs of the different partners.

A performance measurement strategy was put in place when the CHVI was approved. However, some activities foreseen in that strategy have not been fully implemented and this is expected to be a challenge at the time of the next evaluation. In addition, the Initiative's logic

model does not clearly identify the linkages between the CHVI components and, as a result, does not contribute to strengthening the synergies among participating departments/agencies.

5.0 Recommendations

There are three main themes in the recommendations arising from this evaluation. They focus on the future of the CHVI, with respect to the scope of the Initiative and partners as a result of, among other things, the recommendation not to move forward with the pilot scale manufacturing facility, addressing the factors that contributed to the delays in the Initiative and strengthening the CHVI governance structure and performance measurement.

Focusing on the Future

There are a number of factors that will affect the nature and scope of the CHVI in the upcoming years, including changes in the external environment for an HIV vaccine initiative and delays in the implementation of CHVI.

As a result of the changes in the HIV vaccine landscape, following the recent failure of a promising HIV vaccine, many respondents suggested that CHVI needs to re-examine the emphasis and approach of the pilot scale manufacturing component. As a result of the evaluation findings, the team would have recommended such a re-examination. However, by the time the data collection had been completed, a recommendation had already been made not to move forward with the development of the pilot scale manufacturing facility, prompting a rethinking of the approach to this component. This change in emphasis has repercussions for both the resources for other components and the CHVI participating departments and agencies.

Respondents were keen to see a rebalancing of the components to provide a greater emphasis on the Discovery and Research component and the regulatory aspects of the Policy, Regulatory, Community and Social component. There may need to be a reassessment of the use of investments that had been committed to the pilot scale manufacturing component.

In addition to reassessing the investments in the pilot scale manufacturing component, some partner agencies or departments may need to reassess their role in the Initiative. This may mean reassessing their investments in the component, or reassessing the use of their investments. The exercise should focus on ensuring greater synergy between the different partners and the departments/agencies.

1. It is recommended that the Interdepartmental Steering Committee take the opportunity of the recommendation of the Government of Canada and the Bill & Melinda Gates Foundation to not proceed with the Pilot Scale Manufacturing Capacity for Clinical Trial Lots component to re-examine the nature and scope of the Initiative and, as individual departments/agencies, to re-examine their commitments to, and roles in, the Initiative, as well as the role of the Bill & Melinda Gates Foundation.

The delays in the implementation of CHVI to date will affect the nature and scope of the CHVI in the remaining years. All components have experienced delays and the current projections for the disbursement of the CHVI funds reflect that the final disbursements will not be made until 2015/16. The strategic rethinking of the Initiative needs to include planning for the continuance of the Initiative beyond its current expiry date of 2012/13.

The process of rethinking the Initiative should take into account the upcoming revisions to the Global Enterprise SSP and the evolving needs in the community. The need for flexibility in the Initiative to address these issues should be a key consideration of the Interdepartmental Steering Committee.

2. It is recommended that the Interdepartmental Steering Committee seek an extension of the Initiative beyond 2012/13, ensuring that there is sufficient flexibility in the Initiative to allow it to remain consistent over time with the global efforts to achieve an HIV vaccine.

Addressing the Delays

Delays in the implementation of all CHVI components have hampered not only the achievement of the expected results but also the reputation of the CHVI in the external community. Although some delays in such initiatives are inevitable, others appear to have resulted from the challenges of interdepartmental decision-making and the lack of synergy among participating departments/agencies.

3. It is recommended that, as part of the re-examination of the nature and scope of the Initiative, the Interdepartmental Steering Committee identify clear expectations and timelines with respect to the delivery responsibilities of the participating departments/agencies in order to overcome the factors that have contributed to the

delays to date in the Initiative.

Communicating with External Stakeholders

The delays in the implementation of the CHVI were not clearly communicated to external stakeholders, resulting in frustration among stakeholders about the lack of transparency and progress. It has been found that the Initiative lost some of the positive momentum generated from early external consultations due to the lack of communication with external stakeholders.

Partners in the Initiative need to agree on proactive approaches to communicating with external stakeholders in the absence of progress and ensure that the information on the website is up-to-date.

4. It is recommended that the Interdepartmental Steering Committee put in place measures to communicate effectively with external stakeholders, through both the CHVI website and clear messaging from the participating departments/agencies.

Strengthening the Governance Structure and Performance Measurement

Delays in the implementation of all CHVI components have been attributed, in part, to the complexity of this horizontal initiative, the lack of explicit agreements between departments/agencies on implementation, the lack of engagement of some stakeholders and high staff turnover in some departments/agencies. This suggests that, to some extent, the CHVI governance structure has not been able to address adequately these issues and, as a result, CHVI has not gained the full benefits of being a horizontal initiative. There are a number of specific issues with respect to the governance structure that need to be addressed to maximize the benefits of the horizontal initiative and allow the Initiative sufficient flexibility to respond to the changes needs in the HIV vaccine environment. These include the nature and role of the senior level governing body, the resources available from core participating departments/ agencies and the Secretariat's resources.

Changes in the senior level governing body are required to strengthen the collaboration among partners and allow for greater flexibility. Alternative governing approaches might be considered to ensure sufficient direction for the Initiative and provide adequate mechanisms for inputs from participating departments/agencies, while also allowing sufficient flexibility to respond to issues in the HIV vaccine environment.

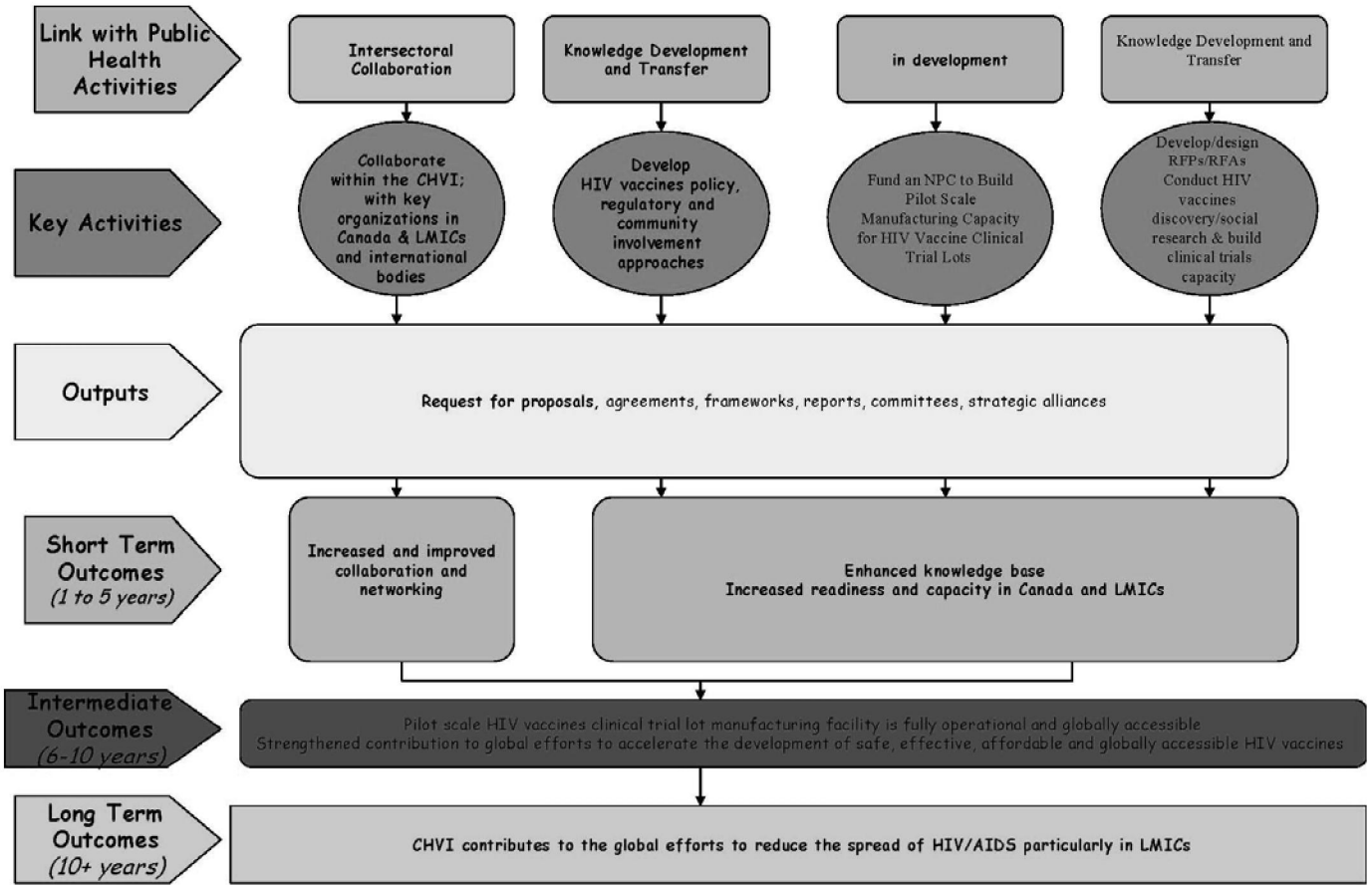
It is important that the governing body for the Initiative address strategic issues. However, the governing body also needs to address the implementation issues (e.g. the lack of explicit agreements between departments/agencies on implementation, the lack of engagement of some stakeholders and high staff turnover in some departments/agencies) facing the engagement of various departments/agencies and identify ways to strengthen the collaboration among partners.

5. It is recommended that the Interdepartmental Steering Committee re-examine the structure of the CHVI governing bodies, notably the Interdepartmental Steering Committee, to ensure that there is adequate authority and capacity to provide the necessary interdepartmental leadership.

The existing CHVI performance measurement framework is not sufficient for identifying the opportunities for collaboration within the Initiative. This requires the development (with the engagement of all departments/agencies) of a more detailed logic model (with accompanying text) that reflects the specific expected outputs and outcomes for each component and how each department/agency contributes to these outputs and outcomes. These revisions would need to reflect any changes that come out of re-thinking of the future of the Initiative and its partners and revisions to the CHVI timeframe. Once a revised framework is available, efforts need to be made to implement it in order to ensure that sufficient data is available for the next evaluation.

6. It is recommended that the Secretariat, working with the program-level Interdepartmental Committee, review the existing CHVI performance framework to ensure that it remains relevant and clearly identifies department/agency responsibilities for all components and the logic model specifically identifies the links across components to the outcomes; and ensure that the performance framework is implemented to provide sufficient data for the next evaluation.

Appendix A: CHVI Logic Model



Source: "Integrated Result-Based Management and Accountability Framework and Risk-based Audit Framework" (RMAF/RBAF), p. 21

Appendix B: Issues Cross-referenced to Evaluation Report Sections

Evaluation Questions	Sections
Implementation Progress	
1) Is funding used fully, effectively and in keeping with plans and authorities?	1.4
2) What activities have been funded?	3.2; Appendix G
3) What client groups and organizations have received funding?	Appendix H
4) What research areas and what research priorities have received funding?	3.2; Appendix H
5) What delivery mechanisms have been used?	3.2; Appendix G
6) Is the program being delivered/ implemented as it was designed?	1.4; 3.2; Appendix G
7) Is the governance structure effective? a) To what extent have the implementation structures been adequate? b) Do they adequately integrate the right stakeholders?	3.5
8) Are collaborative arrangements between departments/ agencies/ Gates foundation effective?	1.3; 1.4; 3.2
9) Are there areas of duplication?	3.2
Achievement of Early Program Results	
10) What progress has been made toward achievement of results?	2.3; 3.2; Appendix G
13) Is there a performance measurement system in place that involves all participating departments?	3.5
Role of CHVI and Ongoing Relevancy	
14) What is required in the current HIV vaccine environment?	3.1; 3.2
15) Consistency with Branch and partner organizations (other Government of Canada) mandate, objectives and priorities?	3.1
16) Consistency with needs and priorities of primary beneficiaries and constituencies?	3.1
Promising Practices and Lessons Learned	
17) Would the CHVI benefit from a reallocation of funding and a change of emphasis between activities?	3.1; 4.0
18) What worked well in the delivery of the research and community initiatives programs?	3.2; Appendix G
19) What were some of the challenges in the community initiatives program?	3.2; Appendix G
20) What worked well in the pilot scale manufacturing facility component?	3.2; Appendix G

Evaluation Questions	Sections
21) What were some of the challenges in the pilot scale manufacturing facility component?	3.2; Appendix G
22) Is CHVI linking well with key stakeholders involved in the HIV vaccine field?	3.2
23) Is CHVI linking well with key stakeholders involved in other areas of the HIV prevention technology field?	3.2
24) Are there ways to improve program delivery from either an effectiveness or efficiency perspective?	3.2; 4.0

Appendix C: List of CHVI Documents

The evaluation team reviewed key program and background documents related to the CHVI, mandate and priorities.

1) CHVI Discovery and Social Research

- Emerging Team Grant: HIV/AIDS Vaccine Discovery and Social Research (RFA from CIHR website)
- Catalyst Grant (RFA from CIHR website), Catalyst Grant Funding Decisions
- CHVI Team Grant in HIV Vaccine Research - Partnership Development
- Forum, Oct. 2008, South Africa, Opening Remarks CHVI Partnership Development Forum
- Funding Opportunity Announcement
- Operating Grant: Fall 2008 Priority Announcement

2) CHVI Pilot Scale Manufacturing Capacity for Clinical Trial Lots

- Documents re: pre-consultation on the facility, web-based consultation on the facility ISA
- CHVI Pilot Scale GIV Vaccine Man. Fac. In Canada for CT lots - Project Management - Briefing SADM March 11, 2009
- Project plan and Schedule Dec. 8/08 version
- Memo to CHVI Interdepartmental Steering Committee on Pilot facility
- LOI form from GoC and Gates for a Pilot facility (April 15, 2008)
- ISA form from GoC and Gates for a Pilot facility (April 15, 2008)
- Funding Opp. Announcement LOI
- Application for Nov. 10, 2008 , plus requirements
- CHVI Facility Project
- RODs for 2008: Sept. 4, Sept. 12, Oct. 8, Oct. 22, Oct. 29, Nov. 12, Dec. 5
- RODs for 2009: Jan. 19, Feb. 16/09, March 11
- Facility binder - contains a folder with miscellaneous information. In the binder are minutes of the Interdepartmental Steering Committee (specific to the facility)

3) CHVI Clinical Trials Capacity Building and Networks

- Concept Note for the Clinical Trials Capacity Building And Networks Component of CHVI (Nov. 26, 2008)

4) CHVI Policy and Regulatory Issues, Community and Social Dimensions

- Concept note on sustainable regulatory development to accelerate access to HIV Vaccines in countries most in need
- Policy Development and Community Engagement Fund deck (Feb. 11, 2008)
- CHVI Community Initiatives Fund - status of ISA (3 bullets - Jan. 12, March 13 and March 2009)
- Community Initiatives Invitation to Submit Applications (June 2008)
- 2 grant reports (outputs):
  - Technical and Financial Report of the AAVP Ethics, Law and HR Collaborating Centre (8 Sept. 2008 - 31 March 2009)
  - Report from UNAIDS to Health Canada (Geneva, Dec. 15, 2008)
    - Health Canada contract outputs:
  - Overview of the Cdn. Patent Landscape of HIV Vaccine-Related Technologies (Nov. 2007)
  - Intellectual Property Management and HIV vaccine-related technologies (July 2007)
    - PHAC contract outputs:
  - Good Participatory guidelines for Biomedical HIV Prevention Trials: A Consultation Plan for Canada (March 31, 2009)
  - Policy Agenda deck (completed April 2009, and summary table)
  - Literature Review: Potential Synergies Between HIV Vaccines, Microbicides and Pre-Exposure Prophylaxis (March 31, 2009)
  - Considerations Regarding Global Access in the Context of the Canadian HIV Vaccine Initiative (April 2008)
  - Integration and Collaboration on the CHVI (March 25, 2008)
  - A Partnership Framework for the CHVI draft 2 (June 15, 2008)
  - CHVI draft interview guide for PPPs (not dated)

5) Planning, Coordination and Evaluation

- Overview deck of the CHVI - Feb. 2009
- Interdepartmental Steering Committee minutes:
  - 2008 minutes: Jan. 28, May 9, Sept. 29, Oct. 21, Oct. 29
  - 2009 minutes: Jan. 27, March 17
    - Interdepartmental Steering Committee Terms of Reference (Jan. 28, 2008)
- CHVI RMAF/RBAF

CHVI Communications Working Group:

- 2007 summary of outcomes: Nov. 13, Nov. 27, Dec. 11
- 2008 summary of outcomes: Jan. 8, March 23
- CHVI Progress from Oct. 2008- end of Jan. 2009
- Conferences attended + all documentation prepared for each.
- CHVI Inaugural Annual Report 2007-08 (Draft Feb. 2, 2009)
- CHVI Annual Report 2008-09 (Draft March 30, 2009)
- CHVI Communications Plan - March-July 2009 (first draft)
- CHVI Communications Strategy (March 4, 2009)
- CHVI Web site

Consultations/Partnership docs:

- Consultation on CHVI Funding Programs (Feb. 10-12, 2008)
- IPM: Information Sharing Session (IPM - Jan. 27 2009), summary of meeting with Minister and IPM Aug. 4, Mexico City
- IAVI - Meeting summary - Minister and IAVI (Aug. 4, 2008, Mexico City); Summary of Info Sharing Session - Feb. 12, 20089, Ottawa; summary of meeting with IAVI and CHVI staff, Aug. 4, Mexico City
- Global HIV Vaccine Enterprise: Funding grant (Feb. 16-2009 - Jan. 31, 2010); summary of meeting with the Global HIV Vaccine Enterprise, Jan. 16/09; Summary of Meeting and Meeting Note with the Global HIV Vaccine Enterprise, Nov. 26/08; Meeting summary - Minister and the Global HIV Vaccine Enterprise, Aug. 5/08, Mexico City; June 20/08 Summary of teleconference with Frank, CHVI and the Global HIV Vaccine Enterprise; Potential Areas of Collaboration (e-mail from Steven, June 20/08); letter of congratulations to the Global HIV Vaccine Enterprise - Dec. 21, 2007.
- Partnership, engagement and linkages framework
- March 19, 2009 deck: CHVI Depts/Agencies and the IDRC: Proposed Working Relationship
- Trip Report - CHVI Delegation - Washington and Philadelphia Jan. 13-15/09
- Feb.2009 deck to AAVP, New York - Overview of the CHVI
- Partnership Development and Stakeholder Engagement Framework for CHVI (Jan. 2009 - approved by DG Steering Committee)
- Draft MOU between Office of HIV Vaccines and BGTD (Revised April 2009), concept paper Formalizing Avaref into Avaren for Discussion (Jan. 7,2009)
- Minutes - National Partners and PHAC Forum - April 16, 2008, Ottawa - 1 page of minutes outlining what CHVI did at the meeting)
- Jan. 8. 2008 - CHVI deck presented to Public Health Network

- Jan. 28, 2008 CHVI deck presented to National Aboriginal Council on HIV/AIDS
- Framework for Bilateral Federal – Provincial Discussions on Collaborative Opportunities re: CHVI (May 9, 2008) + Feb. 1/08 Letter from Kerri Irvin Ross (Manitoba) and letter to her from Tony Clement + Jan. 4/08 letter from George Abbott (BC Min of Health) to Minister Clement.
- MOU between Bill & Melinda Gates Foundation and Government of Canada
- Office of HIV Vaccines (PHAC) Contract Outputs
- Office Of HIV Vaccines Team Building Retreat - April 8, 2008
- Deck for the 15th Canadian Conference on International Health, Ottawa, Oct. 26-28
- CHVI Facility teleconference minutes with Bill & Melinda Gates Foundation (Dec. 1, 208 and May 5, 2008)
- Minutes/Meeting summaries with Gates the Foundation
- Agendas/meeting minutes of the CHVI Community, Policy, Regulatory Sub-Committee

Appendix D: Summary of Key Informant Interviews

INTERNAL STAKEHOLDERS	
Agency/ Department	*Number of Interviewees*
Canadian International Development Agency	3
Public Health Agency of Canada	7 *(including 3 CHVI representatives)*
Industry Canada	4
Canadian Institute for Health Research	4
Health Canada	2
Total	20
EXTERNAL STAKEHOLDERS	
Organization/Agency	*Number of Interviewees*
The Global HIV Vaccine Enterprise	1
National Institutes of Health	2
AIDS Vaccines Advocacy Coalition (AVAC)	1
World Health Organization	1
The Bill &Melinda Gates Foundation	1
African AIDS Vaccine Programme (AAVP)	1
Researchers at Canadian universities	5
Canadian AIDS Society	2
Interagency Coalition on AIDS and Development (ICAD)	1
Canadian HIV Trials Network	1
Other HIV Vaccine Experts	2
Biomedical Private Sector Representatives	2
Total	20

Appendix E: Internal Stakeholders Interview Guide

CHVI Office, Other PHAC Staff, and CHVI Committee Members – Interview Guide

The Office of HIV Vaccines has retained the services of the management consulting firm Goss Gilroy Inc. (GGI) to conduct a formative Evaluation of the Canadian HIV Vaccine Initiative (CHVI). The purpose of the evaluation is to assess the progress of the CHVI in the first two years of implementation. The evaluation will look at progress made to date by the initiative and determine if changes are required to the design, delivery and direction of the initiative or program areas.

The evaluation involves comprehensive interviews as well as a document and file reviews. In the evaluation, interviews are being conducted with key stakeholders.

Your participation in this interview is voluntary, and your responses will be treated confidentially by GGI. Results will be reported at an aggregate level only. The interview will take approximately 45-60 minutes to complete, depending on your level of involvement with the CHVI.

Introduction

1. Please describe your role in your department and with the CHVI.
    a. Since when have you been involved with the CHVI?

Probe: - Past involvement
- Involvement in different CHVI components

2. Is the CHVI program consistent with the mandate, objectives, and priorities of your department/ agency and other departments/agencies involved (HC, CIHR, CIDA, IC)? (Issue 15)
    a. If no, what changes do you recommend for CHVI to become consistent?
    b. Ask for additional relevant documentation

CHVI Discovery and Social Research

Implementation Progress

3. What progress has been made toward achievement of results in the CHVI Discovery and Social Research program area? (Issue 10)
    a. Barriers or challenges to progress towards the implementation of this component?
    b. If there have been delays, what are the reasons for these delays? What should have or could have been done differently to avoid these delays?
    c. What have been the successes?

4. *(If not addressed in Question 2)* What worked well in the RFP/RFA/LOI process for research programs? (Issue 18)
    a. What were some of the challenges?

5. To what extent are collaborative arrangements between CHVI and other government of Canada agencies and departments effective (e.g. CIHR, CIDA)? (Issue 8)
    a. Can you suggest improvements in these collaborative arrangements? (Issue 8)

6. Are there any areas of duplication between the activities of Discovery and Social Research program area and activities in other organizations? (e.g. as other government departments or agencies or other)? (Issue 9)
    a. If so, do you have any suggestions for addressing this/ these areas of duplication?

CHVI Pilot Scale Manufacturing Capacity for Clinical Trial Lots

Implementation Progress

7. What progress has been made toward achievement of results for the CHVI Pilot Scale Manufacturing Capacity for Clinical Trial Lots program area? (Issue 10 and 21)
    a. Barriers or challenges to progress towards the implementation of this component?
    b. If there have been delays, what are the reasons for these delays? What should have or could have been done differently to avoid these delays?
    c. What have been the successes?

8. *(If not addressed in Question 7)* What worked well in the RFP/RFA/LOI process for the Pilot Scale Manufacturing facility? (Issue 18)
    a. What were some of the challenges?

9. To what extent are collaborative arrangements between CHVI and other government of Canada agencies and departments effective (e.g. IC, PHAC)? (Issue 8)
    a. Can you suggest improvements in these collaborative arrangements?

10. To what extent are collaborative arrangements between CHVI and external stakeholders (e.g. the **Bill &Melinda Gates Foundation**) effective?
    a. Can you suggest improvements in these collaborative arrangements? (Issue 8)

11. Are there areas of duplication between the CHVI and other organizations? (e.g. as other government departments or agencies or other)? (Issue 9)
    a. If so, do you have any suggestions for addressing this/ these areas of duplication?

CHVI Clinical Trials Capacity Building and Networks

Implementation Progress

12. What progress has been made toward achievement of results in the Clinical Trials Capacity Building and Networks program? (Issue 10)
    a. Barriers or challenges to progress towards the implementation of this component?
    b. If there have been delays, what are the reasons for these delays? What should have or could have been done differently to avoid these delays?
    c. What have been the successes?

13. To what extent are collaborative arrangements between CHVI and other government of Canada agencies and departments effective (e.g. CIDA, IDRC)? (Issue 8)
    a. Can you suggest improvements in these collaborative arrangements?

14. To what extent are collaborative arrangements between CHVI and external stakeholders (Global Health Research Initiatives, etc.) effective? (Issue 8)
    a. Can you suggest improvements in these collaborative arrangements?

15. Are there areas of duplication between the CHVI Clinical Trials Capacity Building and Networks activities and that of other organizations? (e.g. as other government departments or agencies or other)? (Issue 9)
    a. If so, do you have any suggestions for addressing this/ these areas of duplication?

CHVI Policy, Regulatory, Community and Social Dimensions

Implementation Progress

16. What progress has been made toward achievement of results? (10)
    a. Barriers or challenges to progress towards the implementation of this component?
    b. If there have been delays, what are the reasons for these delays? What should have or could have been done differently to avoid these delays?
    c. What have been the successes?

17. *(If not addressed in Question 18)* What worked well in the RFP/RFA/LOI process for the Community Initiatives Fund? (Issue 18)

18. To what extent are collaborative arrangements between CHVI and other government of Canada agencies and departments effective (e.g. HC and PHAC)? (Issue 8)
    a. Can you suggest improvements in these collaborative arrangements?

19. To what extent are collaborative arrangements between CHVI and external stakeholders (WHO, AAVP, UNAIDS, similar Non-profit organizations, etc.) effective? (Issue 8)
    a. Can you suggest improvements in these collaborative arrangements?

20. Are there areas of duplication between the Policy, Regulatory, Community and Social Dimensions activities and that of other organizations? (e.g. as other government departments or agencies or other)? (Issue 9)
    a. If so, do you have any suggestions for addressing this/ these areas of duplication?

CHVI Planning, Coordination, and Evaluation

Achievement of Early Program Results

21. What progress has been made in the planning, coordination and evaluation component of CHVI? (Issue 10)
    a. Barriers or challenges to progress towards the implementation of this component?
    b. What have been the successes?

22. To what extent are/were the following effective? (Issue 7)
    a. The CHVI **Interdepartmental Steering Committee**?
        i. What works well with this committee
        ii. What are some of the challenges or areas for improvement?
    b. The CHVI **Secretariat**?
        i. What works well with the Secretariat
        ii. What are some of the challenges or areas for improvement?
    c. The CHVI **Interdepartmental Committee**?
        i. What works well with this committee
        ii. What are some of the challenges or areas for improvement?
    d. The CHVI **Communication Working Group**?
        i. What works well with this committee
        ii. What are some of the challenges or areas for improvement?

Note: Ask ONLY of CHVI Staff

23. Can you describe the CHVI performance measurement system? (Issue 13)
    a. Who is involved in this system?
    b. How is it being used?

ASK OF ALL RESPONDENTS

Role of CHVI, Ongoing Relevancy and Promising Practices

24. What programs and services are currently required in the HIV vaccine environment? (Issue 14)
    a. Is CHVI consistent with these needs? (Issue 16)
    b. What changes do you recommend to ensure that CHVI becomes more/ remains consistent with these needs?

25. Is CHVI linking well with key stakeholders involved in the HIV vaccine field? (Issue 22)
    a. If not, what changes do you recommend for CHVI to better link with key stakeholders?

Ask only if respondent is familiar with HIV prevention field (e.g. microbicides)

26. Is CHVI linking well with key stakeholders in other areas of the HIV prevention technology field? (Issue 23)
    a. If not, what changes do you recommend for CHVI to better link with key stakeholders?

27. Is the balance of funding between the different CHVI program areas appropriate? (Issue 17)
    a. What changes or reallocations would you recommend?

28. Can you suggest way to improve the effectiveness or efficiency of the CHVI program delivery? (Issue 24)

Appendix F: External Stakeholders Interview Guide

CHVI Office, Other PHAC Staff, and CHVI Committee Members – Interview Guide

The Office of HIV Vaccines has retained the services of the management consulting firm Goss Gilroy Inc. (GGI) to conduct a formative Evaluation of the Canadian HIV Vaccine Initiative (CHVI). The purpose of the evaluation is to assess the progress of the CHVI in the first two years of implementation. The evaluation will look at progress made to date by the initiative and determine if changes are required to the design, delivery and direction of the initiative or program areas.

The evaluation involves comprehensive interviews as well as a document and file reviews. In the evaluation, interviews are being conducted with key stakeholders.

Your participation in this interview is voluntary, and your responses will be treated confidentially by GGI. Results will be reported at an aggregate level only. The interview will take approximately 20-30 minutes to complete, depending on your level of involvement with the CHVI.

Introduction

1. Please describe your involvement with the CHVI and how it connects with your responsibilities in your organization.

Probe: Involvement in different CHVI components/ Existence of collaborative arrangements.

NOTE: Participants may not know the exact name of the component they are/were involved with. Check for information about the involvement/ area of expertise of each respondent.

ASK OF ALL RESPONDENTS

Role of CHVI, Ongoing Relevancy and Promising Practices

1. What programs and services are currently required in the HIV vaccine environment? (Issue 14)
    a. Is CHVI consistent with these needs? (Issue 16)
    b. What changes do you recommend to ensure that CHVI becomes more/ remains consistent with these needs?

2. Is CHVI linking well with key stakeholders involved in the HIV vaccine field? (Issue 22)
    a. Is yes, which ones and how?

b. If not, what changes do you recommend for CHVI to better link with key stakeholders?

3. (*Ask only if respondent is familiar with HIV prevention field (e.g. microbicides)* Is CHVI linking well with key stakeholders in other areas of the HIV prevention technology field? (Issue 23)
    a. If not, what changes do you recommend for CHVI to better linking with key stakeholders?

4. (*Ask only of participants in organizations that have collaborative arrangements)* To what extent are collaborative arrangements between your organization and CHVI effective? (Issue 8)
    a. Can you suggest improvements in these collaborative arrangements?

CHVI Discovery and Social Research

Description of component (share with interviewees as needed): (1) the discovery of HIV vaccines and related issues (e.g., mucosal and innate immunity); and (2) social and behavioural issues around HIV vaccines (e.g., accessibility to, and acceptability of, vaccines and cultural and other sensitivities to HIV vaccine use).

A key objective in this program area is to promote greater collaboration between researchers in Canada and in LMICs who are working in HIV vaccine discovery and social research. To maximize the potential for important scientific discoveries, a multi-pronged approach is being used to support creativity by both individual investigators and collaborative teams.

Implementation Progress

5. How does this component contribute to the global effort toward an HIV vaccine?

6. (*ask only of participants who are very involved)* What progress has been made in the CHVI Discovery and Social Research program area? (Issue 10)
    a. Barriers or challenges to progress towards the implementation of this component?
    b. If there have been delays, what are the reasons for these delays? What should have or could have been done differently to avoid these delays?
    c. What have been the successes?

7. Are there any areas of duplication between the activities of Discovery and Social Research program area and activities in other organizations? (e.g. as other government departments or agencies or other)? (Issue 9)
    a. If so, do you have any suggestions for addressing this/ these areas of duplication?

CHVI Pilot Scale Manufacturing Capacity for Clinical Trial Lots

Description of component (share with interviewees as needed): CHVI is to contribute funds to a not-for-profit corporation (NPC) to build and govern a pilot scale facility in Canada to manufacture promising HIV vaccine candidates for clinical trials to be conducted mostly in, and for the benefit of, LMICs. The pilot scale manufacturing facility will produce clinical trial lots for HIV vaccine candidates discovered by researchers around the world.

Implementation Progress

8. How does this component contribute to the global effort toward an HIV vaccine?

9. What progress has been made in the CHVI Pilot Scale Manufacturing Capacity for Clinical Trial Lots? (Issue 10 and 21)
    a. Barriers or challenges to progress towards the implementation of this component?
    b. If there have been delays, what are the reasons for these delays? What should have or could have been done differently to avoid these delays?
    c. What have been the successes in the RFP/RFA/LOI process for the Pilot Scale Manufacturing facility? (Issue 18)
    d. What were some of the challenges?

10. Are there areas of duplication between the CHVI Pilot Scale Manufacturing Capacity for Clinical Trial Lots and other organizations? (e.g. as other government departments or agencies or other)? (Issue 9)
    a. If so, do you have any suggestions for addressing this/ these areas of duplication?

CHVI Clinical Trials Capacity Building and Networks

(Description of component (share with interviewees as needed): The Clinical Trial Capacity Building and Networks program area aims to strengthen the capacity of researchers and research institutions to conduct high-quality clinical trials and to build site capacity to undertake clinical trials of HIV vaccines and other preventive technologies in LMICs.

Implementation Progress

11. How does this component contribute to the global effort toward an HIV vaccine?

12. What progress has been made in the Clinical Trials Capacity Building and Networks component? (Issue 10)
    a. Barriers or challenges to progress towards the implementation of this component?
    b. If there have been delays, what are the reasons for these delays? What should have or could have been done differently to avoid these delays?
    c. What have been the successes in the RFP/RFA/LOI process for the clinical trials

capacity building and networks? (Issue 18)
   d. What were some of the challenges?

13. Are there areas of duplication between the CHVI Clinical Trials Capacity Building and Networks activities and that of other organizations? (e.g. as other government departments or agencies or other)? (Issue 9)
    a. If so, do you have any suggestions for addressing this/ these areas of duplication?

CHVI Policy, Regulatory, Community and Social Dimensions

Description of component (share with interviewees as needed): Aims to strengthen vaccine policy approaches that promote global access to HIV vaccines; enhance the regulatory pathway and processes for HIV vaccines in LMICs; collaborate with partners in Canada and LMICs to advance legal, ethical and human rights dimensions of HIV vaccines; and strengthen existing mechanisms to support community involvement in vaccine research and development, clinical trials and activities related to public awareness, education and participation.

Implementation Progress

14. How does this component contribute to the global effort for an HIV vaccine?

15. What progress has been made in the CHVI Policy, Regulatory, Community and Social Dimensions component? (10)
    a. Barriers or challenges to progress towards the implementation of this component?
    b. If there have been delays, what are the reasons for these delays? What should have or could have been done differently to avoid these delays?
    c. What have been the successes?
    d. Did CHVI reach the right community organizations?
    e. What have been the successes in the RFP process for the CHVI Policy, Regulatory, Community and Social Dimensions component? (Issue 18)
    f. What were some of the challenges?

16. Are there areas of duplication between the Policy, Regulatory, Community and Social Dimensions activities and that of other organizations? (e.g. as other government departments or agencies or other)? (Issue 9)
    a. If so, do you have any suggestions for addressing this/ these areas of duplication?

ASK OF ALL RESPONDENTS

17. Can you suggest other ways to improve the effectiveness or efficiency of the CHVI program delivery? (Issue 24)

Appendix G: Implementation Progress for CHVI Components

Component	Progress
CHVI Discovery & Social Research *$22 million over six years* Lead: CIHR	**Purpose:** To strengthen research and research capacity focused on: discovery of HIV vaccines and related research (such as immune correlates, innate and adaptive immunity, T and B cell responses, antigens, adjuvants, vectors, etc.); and social, behavioural and ethical issues in HIV vaccines (e.g. accessibility to, and acceptability of, vaccines and cultural and other sensitivities to HIV vaccine use). **Objectives:** A key objective in this program area is to promote greater collaboration between researchers in Canada and in LMICs who are working in HIV vaccine discovery and social research. To maximize the potential for important scientific discoveries, a multi-pronged approach is being used to support creativity by both individual investigators and collaborative teams. • Create international recognized teams of Canadian and LMIC researchers. • Support individual or small teams of Canadian investigators in their efforts to contribute important knowledge to the global search for HIV vaccines. • Build capacity for HIV vaccines research in Canada and LMICs. • Create mechanisms for CHVI investigators and teams to collaborate with one another and other relevant international networks and consortia. **Progress:** Catalyst Grants: were launched August and December 2008. 11 applications were received (7 in the first round and 4 in the second), of which 8 were funded (5 and 3). A third funding opportunity was launched in July 2009, with funding decisions not yet made on the applications. The focus of catalyst grants was on short-term seed money to support innovative HIV vaccine-related research activities resulting in the development of new proposals, tools, techniques, inventions or methodologies. Operating Grants which were launched June 2008: 7 applications were received and 2 were funded (and an additional 3 funded through CIHR's regular funding mechanisms). Ten more applications were received and an additional 3 operating grants, totalling approximately $1.8M, were approved under the December 2008 launch of the Operating Grant competition. The focus of these grants were on funding Canadian researchers with an interest in basic and social research related to HIV vaccines, to enhance research in HIV prevention and build future Canadian research capacity in the field. Emerging Team Grants (for Canadian teams): Letter of Intent process was launched in May 2009. Review of applications is pending. The Emerging Team Grant was launched to address delays in the launch of the Large Team Grant. Emerging Team Grants support the work of Canadian research teams and their work to strengthen capacity, develop expertise and strategies for knowledge translation and exchange, provide a superior training and mentoring environment, and create mechanisms for individual investigators and teams funded under the initiative to network and share information with one another.

Component	Progress
	Large Team Grants (for international collaborations, funded jointly by CIHR and CIDA): The Grants were included in the original CHVI design, and were discussed at the February 2008 conference. However, the funding has not been finalized, so no Request for Application has yet been announced. The Large Team grants are now expected to be launched in the spring of 2010. Large Team Grants support teams of Canadian and Low- and Middle-Income Country (LMIC) researchers in their efforts to contribute important knowledge to the global search for HIV vaccines, build capacity (human and infrastructure) for HIV Vaccines discovery and related social research in Canada and in LMICs, provide opportunities for new and young investigators and create mechanisms for teams funded under the initiative to network and share information with one another. Travel Awards: CIHR funded travel awards totalling $48,000 to facilitate six researchers' participation in CHVI's Partnership Development Forum during the Oct. 2008 AIDS Vaccine Conference in Cape Town South Africa.
CHVI Pilot Scale Manufacturing Capacity for Clinical Trial Lots *$61.1 million over five years from the Government of Canada and $28 million over five years from the Bill & Melinda Gates Foundation*	**Purpose:** A key priority for the CHVI is to contribute funds to a not-for-profit corporation (NPC) to build and govern a pilot scale facility in Canada to manufacture promising HIV vaccine candidates for clinical trials to be conducted mostly in, and for the benefit of, LMICs. The pilot scale manufacturing facility will produce clinical trial lots for HIV vaccine candidates discovered by researchers around the world. In so doing, the facility will serve as a resource for global HIV vaccine efforts in line with the principles of global access. The establishment of the facility will help address the critical global shortage of HIV vaccine manufacturing capacity for clinical trial lots, thus contributing significantly to efforts to accelerate the development of a safe, effective, affordable and globally accessible HIV vaccine for those who need it the most. The facility will also advance Canada's position as a centre for biomedical innovation and manufacturing, health sciences research and responsiveness to public health challenges. **Objective:** To establish a dedicated pilot scale manufacturing facility in Canada to produce HIV vaccine candidates for use in Phases I, II, III clinical trials, to be conducted mostly in and for the benefit of LMICs. The facility will be operated by a not for profit corporation (with private sector and other partners). **Progress:** Letter of Intent: To help guide the process, a consultation process with key stakeholders as held in Ottawa in February 2008. The funding opportunity was launched in April 2008 as a call for Letters of Intent. 5 Letters were received in June 2008, reviewed by an external committee of experts. Four of the applicants to the Letters of Intent process were invited to submit full applications respecting the March 2009 deadline. Request for Applications: An external review committee examined the 4 applications in May 2009, and made recommendations to the Steering Committee. These recommendations were reviewed by the Steering Committee for the Facility and a recommendation made to not proceed with the facility. If confirmed, this is expected to be announced early in 2010.

Component	Progress
CHVI Clinical Trials Capacity Building & Networks *$16 million over five years* Lead: CIDA	**Purpose:** To strengthen the capacity of researchers and research institutions to conduct high-quality clinical trials and to build site capacity to undertake clinical trials of HIV vaccines and other preventive technologies in LMICs. To fill a globally recognized gap in HIV vaccine clinical trial capacity as identified by the Global HIV Vaccine Enterprise, particularly in LMICs where trials are ongoing or planned; and build on the Global Health Research Initiative (GHRI) Canada-Africa HIV Prevention Trials Capacity Building Program. This component does not aim to support HIV prevention clinical trials themselves. **Objectives:** • establish or enhance collaboration between LMICs and Canadian researchers conducting clinical trials; • enhance individual and institutional capacity in LMICs and Canada to conduct clinical trials of HIV vaccines and other prevention technologies; • provide training or develop models, best practices and information-sharing protocols between researchers and the community; • identify, recruit and retain cohorts of participants in LMICs, where HIV incidence and prevalence rates are high and clinical trials of HIV vaccines and other prevention technologies are planned or are ongoing; and • examine regulatory/safety, community and social issues around HIV clinical trials. **Progress:** Completed a consultation process concerning funding priorities for this component in February 2008. IDRC will provide funds to GHRI for "Capacity Building" and "Synergy and Networking" grants. There have been delays in transfer of funds from CIDA to IDRC but CIDA has signed a grant agreement to provide $6M of the $16M previously approved (an agreement was signed January 2009). The first call for Capacity Building Grant Letters of Intent was launched in July 2009, to help applicants build on established partnerships to develop sustainable African capacity and leadership to conduct future HIV/AIDS prevention trials. This process closes in September 2009, and results are expected to be released by March 2010.
CHVI Policy and Regulatory Issues, Community and Social Dimensions *$8.46 million over 5 years* Lead: PHAC	**Purpose:** To address policy, regulatory, community and social dimensions related to the development of a safe, effective, affordable and globally accessible HIV vaccine. **Objective:** • improved domestic and international policy development models, capacity and tools to address HIV vaccine-related issues; • enhanced global access to evidence-based tools and knowledge regarding the community and social dimensions of HIV vaccine research; and • improved regulatory capacity in LMICs, especially those where clinical trials are planned or are ongoing;

Component	Progress
	• enriched policy dialogue and discourse surrounding the legal, ethical and human rights dimensions related to the HIV vaccine; • greater meaningful engagement and participation of local communities in all aspects of the HIV vaccine research and development continuum; and • greater awareness amongst local communities of their rights and the benefits and potential risks associated with HIV vaccine research. **Progress:** Policy & Regulatory: Grants were awarded to WHO AAVP to strengthen the ethical-legal framework for HIV vaccine trials and to UNAIDS to support dissemination and translation to promote *Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials*. Grant recipients presented the results of their work in a satellite session sponsored/hosted by HC and PHAC at the Canadian Association of HIV Research Conference 2008 in Vancouver. CIDA has received a proposal ($2M) to conduct a project to build sustainable regulatory capacity in low and middle-income countries. The proposal is currently being reviewed. Consultations on the CHVI Policy Agenda were completed in early 2009/10. The deck was shared with all partners and the international experts who were interviewed. The input received will help shape a draft policy agenda for the CHVI which will be prepared in fall 2009. A public-private partnership paper is in development, and a final report is expected at the end of September 2009. The paper will explain how public private partnerships could be structured to effectively engage partners. A literature review on synergies between new HIV prevention technologies (NPTs) has been developed. The paper will assist the CHVI in defining possible linkages with other NPTs and opportunities for collaboration and knowledge exchange. Three abstracts were submitted and accepted as poster presentations at the AIDS Vaccine 2009 Conference in Paris in October. The CHVI has also been invited to participate in a panel discussion hosted by the AIDS Vaccine Advocacy Coalition. Community Initiatives fund launched in January 2009, with a March 2009 closing date. Two applications were received and the project has an expected start date of September. CHVI has communicated with organizations directly to obtain additional/ complementary proposals and they are expected to arrive in August. They will be reviewed and projects are expected to start in December 2009.

Component	Progress
Planning, Coordination, and Evaluation *$3.38 million over 5 years* Lead: CHVI (PHAC)	**Purpose:** To ensure effective strategic planning, scientific oversight, coordination and evaluation to meet CHVI objectives. **Objective:** • establish and maintain a governance (decision-making) structure for the CHVI; • monitoring key trends in HIV vaccine research and development; • enhancing Canada's contribution to the global efforts by mobilizing expertise, partnerships, resources and liaising with domestic and international stakeholders (e.g., researchers, academics, the private sector); • establish new partnerships and promote stakeholder engagement in the CHVI; • raise the profile of the CHVI among stakeholders in Canada and internationally and to communicate progress. • provide secretariat support to the CHVI, including its Interdepartmental Steering Committee and multi-stakeholder advisory committee; and • report on progress under the CHVI. **Progress:** Helped build international partnerships and networks by attending conferences such as the AIDS Vaccine 2008 Conference in Cape Town, the XVIII International AIDS Conference in Mexico, and the BIO International Convention 2008 in San Diego (e.g AAVP, WHO, GHE, IAVI, AVAC, NIH, USAID, HVTN and Gates), and hosting the IPM and IAVI during information sessions in early 2009. In addition, members of the CHVI participating departments were invited to the United States to conduct site visits at the NIH Vaccine Pilot Plant, the Merck West Point Facility, and the Aeras Global TB Vaccine Foundation and to attend meetings with representatives from International Partnership of Microbicides, National Institutes of Health and USAID. Funding agreement in place (July 2009) with Global HIV Vaccine Enterprise to support program delivery and the next international AIDS Vaccine Conference (CHVI will be co-sponsor of 9th Annual AIDS Vaccine Conference in October 2009). Working with HC 's Biologics and Genetic Therapies Directorate to develop an MOU to collaborate on HIV vaccine-related issues. Under this MOU, PHAC, HC and CIDA will work together to implement a Regulatory Capacity Building Project, develop quarterly reports on global scientific trends and developments in HIV vaccine-related research, contribute expertise to the establishment in Canada of a pilot scale manufacturing facility for promising HIV vaccine candidates, and contribute expertise to global HIV vaccine regulatory-related activities under the umbrella of the Global HIV Vaccine Enterprise. Completed the first Communications Strategy and Communications Plan

Appendix H: Results of Grant Awards

Catalyst Grant

Memorial University of Newfoundland ($100,000, 1 year) – Heteroclitic Peptides to Increase Human Immunodeficiency Virus-specific CD8+ T cell Interleukin-2 Production

Institut de recherches cliniques de Montréal ($100,000, 1 year) – Dissecting the mechanisms of protection by attenuated Nef-deleted HIV vaccine

Université Laval ($100,000, 1 year) – Promoting innate immunity to HIV infection by vaccine delivery of third generation RNA analogs

McMaster University ($100,000, 1 year) – Functional correlate of mucosal antibody response to HIV infection in blood

Université Laval ($100,000, 1 year) – A new human cell experimental system for evaluating prototype HIV-1 vaccines

Mario Ostrowski, University of Toronto ($99,252) – Discovery of new B cell immunogens for HIV vaccines

University of Saskatchewan ($89,482) – A combined early and late HIV-1 protein-specific exosome-targeted T cell vaccine capable of stimulating HIV-1 specific CD8+ CTL responses in absence of CD4+ T cells and counteracting immune suppression

University of Manitoba ($100,000) – Attacking HIV protease cleavage sites with immunization - Explore the rapid mutation rate of HIV-1

Operating Grants

The Research Institute of the McGill University Health Centre ($440,604, 3 years) – The functional profile of NK cells in HIV exposed uninfected subjects: Association with carriage of NK receptor-HLA ligand genotypes.

Jewish General Hospital, Montreal ($327,993, 3 years) – The potential of APOBEC3G in the development of a novel anti-HIV-1 therapeutic

University of Manitoba ($663,050, 5 years) – The effect of the CD4 pathogenicity island on HIV susceptibility and disease progression

Jewish General Hospital, Montreal ($721,347, 5 years) – Studying the antiviral activity of bone marrow stromal cell antigen 2 and the countering mechanism from HIV-1 Vpu

Université Laval ($391,824, 3 years) – A comparative immunogenicity study of HIV-1 Pr160Gag-Pol virus-like particles bearing gp120, CD40L and/or TLR5 agonist flagellin

Emerging Team Grants

(Approved to submit a full application – awards expected March 2010)

University of Manitoba ($10,000) – Research on the social and cultural aspects of implementing HIV vaccine programs among MSM and FSWs in Asia and Africa

University of Toronto ($10,000) – HIV Vaccine Design based on Novel Strategies to induce Protective Mucosal Cellular and Humoral Immunity

University of Toronto ($10,000) – Enhancing Care and Prevention in HIV Vaccine Trials: An International, Interdisciplinary Collaboration

Simon Fraser ($10,000) – Prophylactic HIV Vaccines for Social Networks of Injection Drug Users

University of British Columbia ($10,000) – At the Crossroads of Vertical and Horizontal HIV Transmission: The HIV-Exposed Uninfected Infant as a Window into Successful HIV Vaccine Design

Health Canada Community Engagement Grants

UNAIDS ($85,000)

WHO African AIDS Vaccine Programme ($95,000)

Community Initiative Grants

Canadian AIDS Society ($268,300.75)

International Coalition on AIDS & Development ($290,000)